Exhibit 1

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ROBERT TORRES

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF LOS ANGELES

UNLIMITED JURISDICTION

ROBERT TORRES,

Plaintiff,

vs.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM FREMONT, INC.; SANOFI US SERVICES, INC.; SANOFI-AVENTIS U.S. LLC.; GLAXOSMITHKLINE, LLC; PFIZER, INC.; WALMART, INC.; COSTCO WHOLESALE CORPORATION; and DOES 1-100, inclusive.

Defendants.

Case No: 21STCV32491

COMPLAINT FOR DAMAGES

1. Strict Products Liability: Failure to Warn
2. Strict Products Liability: Design Defect
3. Strict Products Liability: Manufacturing Defect
4. Negligence – Failure to Warn
5. Negligent Product Design
6. Negligent Manufacturing
7. General Negligence
8. Negligent Misrepresentation
9. Breach of Express Warranties
10. Breach of Implied Warranties
11. Violation of Consumer Protection and Deceptive Tarde Practices Laws
12. Unjust Enrichment

DEMAND FOR JURY TRIAL

INTRODUCTION

1. Zantac is the branded name for ranitidine, a "blockbuster" drug that was sold as a safe and effective antacid. But ranitidine is anything but safe. It is an unstable molecule that, under normal conditions, breaks down into high levels of NDMA, a carcinogen that is as potent as it is dangerous. After almost four decades and billions of dollars of sales, ranitidine consumption has caused hundreds of thousands of consumers to develop cancer. Plaintiff Robert Torres (hereafter "Plaintiff") brings this action for personal injuries as a result of Defendants' design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of brand-name and generic ranitidine-containing products.

2. Until its recent recall by the FDA, ranitidine was a popular antacid drug consumed by millions of people every day. Recent scientific studies, however, confirm what drug companies knew or should have known decades earlier: ingesting ranitidine exposes the consumer to staggering amounts of NDMA.

3. NDMA is a potent human carcinogen. It was first discovered in the early 1900s as a byproduct of manufacturing rocket fuel. Today, its only use is to induce tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It has no medicinal purpose whatsoever.

4. NDMA is not akin to other compounds that have a salutary effect at low levels and a negative effect with greater exposure. There is no recommended daily dose of NDMA. The ideal level of exposure is zero. Nonetheless, the FDA previously set an allowable daily limit of NDMA of 96 nanograms (ng) to minimize the risks posed by this dangerous molecule. Yet a single pill of ranitidine can contain quantities of NDMA that are hundreds of times higher than the allowable limit.

5. These recent revelations by the scientific community have caused widespread recalls of ranitidine both domestically and internationally. In fact, after numerous voluntary recalls, on April 1, 2020, the FDA ordered the immediate withdrawal of all ranitidine-containing products sold in the United States, citing unacceptable and unpreventable levels of NDMA accumulation.

6. The high levels of NDMA observed in ranitidine-containing products is a function of the drug's unstable nature. Ranitidine-containing products generate NDMA as the ranitidine molecule (1) breaks down in the human digestive system; (2) interacts with various

enzymes in the human body; (3) reacts over time under normal storage conditions and which increases significantly when exposed to heat; and/or (4) during the manufacturing process. In aggregate, ranitidine-containing products were akin to billions of Trojan horses that smuggled dangerously high levels of NDMA into the bodies of millions of consumers.

7. Zantac wreaked such widespread harm in large part because Glaxo—the inventor of ranitidine—succumbed to a temptation that is all too familiar to pharmaceutical innovators: maximizing the profits of an incredibly lucrative, government-conferred monopoly.

8. To encourage pharmaceutical companies to invest in research and development ("R&D"), the U.S. legal and regulatory system offers drug companies who invent "new chemical entities" two powerful inducements. First, innovators obtain patent protection for their pharmaceutical compounds. Second, approved new drugs enjoy FDA exclusivity, irrespective of whether the molecule is protected by one or more issued patents. Taken together, these policies assure that a pharmaceutical innovator will receive the exclusive right, for a limited period of time, to sell its drug to the American public.

9. The argument for monopoly pharmaceutical franchises rests on the profit-motive. R&D is time consuming and expensive, and not all drug-development efforts will succeed. Once a drug is approved, some period of monopoly profits is necessary to allow innovators to recoup their sunk R&D costs in both successful and unsuccessful pursuits.

10. In some ways, the system works as intended. Pharmaceutical companies do invent new and useful medicines that—absent high profit potential—might not otherwise come to market. But once an innovator possesses a blockbuster monopoly franchise, it has a virtual license to mint money. Most pharmaceutical ingredients are cheap commodities, which branded manufacturers then resell at a monopoly markup. During the exclusivity period, brand-name drugs routinely enjoy gross profit margins of 70, 80, or even 90+ percent. No other industry comes close to matching this profit-generating potential.

11. As a result of these economic realities, branded drug manufacturers have a strong— and too often perverse—incentive to sell as much product as they can during their exclusivity window. That is why branded manufacturers spend billions of dollars per year in sales and marketing efforts to push incremental sales of a brand-name drug. Where every $1 in new sales can produce upwards of $.90 in gross profit, staggering sales and marketing budgets are a very profitable investment. But while it makes sense for branded manufacturers to spend vast sums of money to develop and promote FDA approved drugs, they have no equivalent

economic or regulatory incentive to uncover and investigate developing risks posed by their products.

12. That problem is especially acute for bestselling, blockbuster drugs. And Zantac is the brand that gave meaning to a blockbuster pharmaceutical product, becoming the first drug ever to generate over $1 billion in annual sales. Zantac's success catapulted Glaxo ahead of its previously larger rivals, fueling the market capitalization and corporate combinations that gave the company its current name: GlaxoSmithKline. It is little wonder Glaxo spared no expense to both get Zantac to market and to aggressively promote it to millions of consumers. Yet Glaxo did not part with a comparative pittance to investigate the obvious cancer risk posed by ranitidine. Turning a blind eye was far more profitable.

13. Ultimately, the law holds every corporate entity in the supply chain of ranitidine responsible for the personal injuries and death caused by such an unsafe product. And the civil justice system is the first, last, and only line of defense against the unchecked avarice that is a byproduct of a regulatory regime with the well-intentioned aim of bringing safe and effective medicines to market. Plaintiff seeks redress both to compensate them for the horrific losses they have suffered in the past and to strongly deter in the future the type of misconduct that gave rise to their injuries.

PARTIES

I. PLAINTIFF ROBERT TORRES

14. Plaintiff is a U.S. citizen and a resident of the County of Los Angeles, in the State of California, who has suffered personal injuries as a result of using Defendants' dangerously defective ranitidine-containing products.

15. Plaintiff was diagnosed with prostate cancer, which was directly and proximately caused by his use of ranitidine-containing products.

II. DEFENDANTS

16. Defendants are collectively composed of entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine.

BRAND-NAME MANUFACTURER DEFENDANTS

17. Defendants BI, GSK, Pfizer, and Sanofi, shall be referred to collectively as the "Brand-Name Manufacturer Defendants." At all relevant times, the Brand-Name Manufacturer Defendants have conducted business and derived substantial revenue from their design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale

of Zantac within each of the States and Territories of the United States, and the District of Columbia.

Boehringer Ingelheim (BI)

18. Defendant Boehringer Ingelheim Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Defendant Boehringer Ingelheim Pharmaceuticals, Inc., is a citizen of Delaware and Connecticut.

19. Defendant Boehringer Ingelheim Fremont, Inc., is a California Corporation with its principal place of business located at 6701 Kaiser Drive, Fremont, CA 94555.

GlaxoSmithKline (GSK)

20. Defendant GlaxoSmithKline LLC is a Delaware limited liability company with its principal place of business located at Five Crescent Drive, Philadelphia, Pennsylvania, 19112. GlaxoSmithKline LLC's sole member is GlaxoSmithKline (America) Inc., a Delaware corporation with its principal place of business in that state. GlaxoSmithKline LLC is a citizen of Delaware.

21. Defendant GlaxoSmithKline (America) Inc. is a Delaware corporation with its principal place of business located at 1105 N. Market Street, Suite 622, Wilmington, Delaware 19801. Defendant GlaxoSmithKline (America) Inc. is a citizen of Delaware.

Pfizer

22. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is a citizen of Delaware and New York.

Sanofi-Aventis

23. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC's sole member is Sanofi U.S. Services, Inc., a Delaware corporation with its principal place of business in New Jersey. Sanofi-Aventis U.S. LLC is a citizen of Delaware and New Jersey.

24. Defendant Sanofi US Services Inc. is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US

Services Inc. is a citizen of Delaware and New Jersey.

25. Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. are subsidiaries of Sanofi Patheon Manufacturing Services LLC and Boehringer Ingelheim Promeco, S.A. de C.V. packaged and manufactured the finished Zantac product for Sanofi. Collectively, these entities shall be referred to as "Sanofi."

26. Defendants DOES 1-100 are herein sued under fictitious names. Their true names and identities are unknown to PLAINTIFF. PLAINTIFF is informed and believes and thereon alleges that Defendants DOES 1-50 are Manufacturers of unknown form. PLAINTIFF is informed and believes and thereon alleges that Defendants DOES 51-100 are Retailers/Repackager of unknown form.

27. The true names and capacities of Defendants 1-100, inclusive, are unknown to PLAINTIFF, who therefore sue the DOE defendants by fictitious names. PLAINTIFF will amend this complaint to show their true names and capacities when they have been ascertained.

28. PLAINTIFF is informed and believes and thereon alleges that there exists, and at all times relevant to this complaint there existed, a unity of interests between certain of the Defendants such that any individuality and separateness between these certain Defendants has ceased, and those certain Defendants are the alter ego of the other certain Defendants and exerted control over each other. Adherence to the fiction of the separate existence of these certain Defendants as an entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and/or promote injustice.

RETAILER/REPACKAGER DEFENDANTS

29. Retailers derived substantial revenue from marketing, handling, distributing, storing, and selling ranitidine-containing products within California. As described below, many retailers also used their own brand names on relabeled ranitidine-containing products.

Walmart

30. Defendant Walmart Inc. f/k/a Wal-Mart Stores, Inc. is a Delaware corporation with its principal place of business located at 702 SW 8th Street, Bentonville, Arkansas 72716. Walmart Inc. is a citizen of Delaware and Arkansas.

31. Defendant Walmart purchased ranitidine and repackaged and/or relabeled it under Defendant's own brand. Therefore, all allegations referring to the "Repackager

Defendants" apply to Defendant Walmart.

Costco Wholesale

32. Defendant Costco Wholesale Corporation ("Costco") is a Washington corporation with its principal place of business located at 999 Lake Drive, Issaquah, Washington 98027. Costco is a citizen of Washington.

33. Defendant Costco purchased ranitidine and repackaged and/or relabeled it under Defendant's own brand. Therefore, all allegations referring to the "Repackager Defendants" apply to Defendant Costco.

JURISDICTION & VENUE

34. The California Superior Court has jurisdiction over this action pursuant to California Constitution Article VI, Section 10, which grants the Superior Court "original jurisdiction in all cases except those given by statute to other trial courts." The statutes under which this action is brought do not specify any other basis for jurisdiction.

35. This Court has personal jurisdiction over Defendants, and each of them since they are and/or were at all relevant times, residents of and/or authorized to conduct business in the State of California. Defendants conducted such business within the State, including the performance of acts that caused or contributed to the harm giving rise to this action. Furthermore, Defendants, and each of them, have sufficient minimum contracts in California and/or principal place of business in California and/or otherwise intentionally avails itself to the California marker so as to render the exercise of jurisdiction over it by this State's courts, as is consistent with traditional notions of fair play and substantial justice.

36. Plaintiff is informed and believes and, on that basis, alleges that Defendants, and each of them, have purposefully availed themselves of the privileges and benefits of conducting activities and business within the forum of the State of California and have invoked the benefits and protections of its laws.

37. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products within the State of California and targeted consumer markets within the County of Los Angeles.

38. At all times alleged herein, Defendants were authorized to conduct or engage in business within the State of California and supplied ranitidine-containing products within the

County of Los Angeles. Defendants received financial benefit and profits as a result of designing, manufacturing, testing, marketing, labeling, packaging, handling, distributing, storing, and/or selling ranitidine-containing products within California.

39. Defendants each have significant contacts in the State of California, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their ranitidine-containing products in the State of California and the County of Los Angeles.

FACTUAL ALLEGATIONS

I. THE CREATION OF RANITIDINE-CONTAINING PRODUCTS AND THEIR INTRODUCTION TO THE MARKET

40. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine under the brand-name Zantac or a generic equivalent by either prescription or over the counter. Defendants sold or otherwise made available ranitidine in the following forms: injection, syrup, granules, tablets and/or capsules.

41. Ranitidine belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by cells in the lining of the stomach. Other drugs within this class include cimetidine (branded Tagamet), famotidine (Pepcid), and nizatidine (Tazac).

42. GSK-predecessor Smith, Kline & French discovered and developed Tagamet, the first H2 blocker and the prototypical histamine H2 receptor antagonist from which the later members of the class were developed.

43. GSK[1] developed Zantac specifically in response to the success of cimetidine. Recognizing the extraordinary potential of having its own H2 blocker in the burgeoning anti-ulcer market, GSK was all too willing to ensure its drug succeeded at all costs.

44. In 1976, scientist John Bradshaw, on behalf of GSK-predecessor Allen & Hanbury's Ltd. synthesized and discovered ranitidine.

45. Allen & Hanbury's Ltd., a then-subsidiary of Glaxo Laboratories Ltd., is credited with developing ranitidine and was awarded Patent No. 4,128,658 by the U.S. Patent and

[1] GSK, as it's known today, was created through a series of mergers and acquisitions: In 1989, Smith, Kline & French merged with the Beecham Group to form SmithKline Beecham plc. In 1995, Glaxo merged with the Wellcome Foundation to become Glaxo Wellcome plc. In 2000, Glaxo Wellcome plc merged with SmithKline Beecham plc to form GlaxoSmithKline plc and GlaxoSmithKline LLC.

Trademark Office in December 1978, which covered the ranitidine molecule.

46. In 1983, the FDA granted approval to Glaxo to sell Zantac, pursuant to the New Drug Application ("NDA") No. 18-703 and it quickly became GSK's most successful product—a "blockbuster." Indeed, ranitidine became the first prescription drug in history to reach $1 billion in sales.

47. To accomplish this feat, GSK entered into a joint promotion agreement with Hoffmann-LaRoche, Inc., increasing Zantac's U.S. sales force from 400 people to approximately 1,200. More salespersons drove more sales and blockbuster profits for GSK.

48. In 1993, GSK (through Glaxo Wellcome plc) entered into a joint venture with Pfizer-predecessor company Warner-Lambert Co. to develop an OTC version of Zantac. In 1995, the FDA approved OTC Zantac 75 mg tablets through NDA 20-520. In 1998, the FDA approved OTC Zantac 75 mg effervescent tablets through NDA 20-745.

49. In 1998, GSK (Glaxo Wellcome plc) and Warner-Lambert Co. ended their joint venture. As part of the separation, Warner-Lambert Co. retained control over the OTC NDA for Zantac and the Zantac trademark in the United States and Canada but was required to obtain approval from GSK prior to making any product or trademark improvements or changes. GSK regained rights to sell OTC Zantac outside of the United States and Canada,[2] and retained controlover the Zantac trademark internationally.

50. In 2000, Pfizer acquired Warner-Lambert Co. Pfizer controlled the Zantac OTC NDAs until December 2006.

51. In October 2000, GSK sold to Pfizer the full rights to OTC Zantac in the United States and Canada pursuant to a divestiture and transfer agreement. As part of that agreement, GSK divested all domestic Zantac OTC assets to Pfizer, including all trademark rights. The agreement removed the restrictions on Pfizer's ability to seek product line extensions or the approval for higher doses of OTC Zantac. GSK retained the right to exclusive use of the Zantac name for any prescription ranitidine-containing product in the United States.

52. In October 2003, Pfizer submitted NDA 21-698 for approval to market OTC Zantac 150 mg. The FDA approved NDA 21-698 on August 31, 2004.

53. Throughout the time that Pfizer owned the rights to OTC Zantac, GSK continued to manufacture the product.

[2] GSK also still held the right to sell prescription Zantac in the United States.

54. In 2006, pursuant to a Stock and Asset Purchase Agreement, Pfizer sold and divested its entire consumer health division (including employees and documents) to Johnson & Johnson ("J&J"). Because of antitrust issues, however, Zantac was transferred to Boehringer Ingelheim.

55. Pfizer, through a divestiture agreement, transferred all assets pertaining to its Zantac OTC line of products, including the rights to sell and market all formulations of OTC Zantac in the United States and Canada, as well as all intellectual property, R&D, and customer and supply contracts to Boehringer Ingelheim. As part of that deal, Boehringer Ingelheim obtained control and responsibility over all of the Zantac OTC NDAs.

56. GSK continued marketing prescription Zantac in the United States until 2017 and still holds the NDAs for several prescription formulations of Zantac. GSK continued to maintain manufacturing and supply agreements relating to various formulations of both prescription and OTC Zantac. According to its recent annual report, GSK claims to have "discontinued making and selling prescription Zantac tablets in 2017 . . . in the U.S."[3]

57. Boehringer Ingelheim owned and controlled the NDA for OTC Zantac between December 2006 and January 2017, and manufactured, marketed, and distributed the drug in the United States during that period.[4]

58. In 2017, Boehringer Ingelheim sold the rights of OTC Zantac to Sanofi pursuant to an asset swap agreement. As part of that deal, Sanofi obtained control and responsibility over Boehringer Ingelheim's entire consumer healthcare business, including the OTC Zantac NDAs. As part of this agreement, Boehringer Ingelheim and Sanofi entered into a manufacturing agreement wherein Boehringer continued to manufacture OTC Zantac for Sanofi.

59. Sanofi has controlled the OTC Zantac NDAs and marketed, sold, and distributed Zantac in the United States from January 2017 until 2019 when it issued a recall and ceased marketing, selling, and distributing OTC Zantac.

60. Throughout the time that Sanofi controlled the OTC Zantac NDAs, Boehringer Ingelheim Promeco, S.A. de C.V. and Patheon Manufacturing Services LLC manufactured the finished drug product.

61. Sanofi voluntarily recalled all brand-name OTC Zantac on October 18, 2019.

62. Pfizer and Boehringer Ingelheim have made demands for indemnification per the

[3] GlaxoSmithKline, plc, *Annual Report* 37 (2019), https://www.gsk.com/media/5894/annual-report.pdf.
[4] Boehringer Ingelheim also owned and controlled ANDA 074662.

Stock and Asset Purchase Agreement against J&J for legal claims related to OTC Zantac products.

63. Sanofi has made a demand for indemnification against J&J pursuant to a 2016 AssetPurchase Agreement between J&J and Sanofi.

II. NDMA IS A PROBABLE CARCINOGEN WHOSE DANGEROUS PROPERTIES ARE WELL ESTABLISHED

64. According to the Environmental Protection Agency ("EPA"), "NDMA is a semi-volatile organic chemical that forms in both industrial and natural processes."[5] It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health. A 1979 news article noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[6] NDMA is no longer produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

65. Both the EPA and the International Agency for Research on Cancer ("IARC") classify NDMA as a probable human carcinogen.[7]

66. The IARC classification is based upon data that demonstrates NDMA "is carcinogenic in all animal species tested: mice, rats, Syrian gold, Chinese and European hamsters, guinea-pigs, rabbits, ducks, mastomys, various fish, newts and frog. It induces benign and malignant tumors following its administration by various routes, including ingestion and inhalation, in various organs in various species." Further, in 1978, IARC stated that NDMA "should be regarded for practical purposes as if it were carcinogenic to humans."[8]

67. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[9]

68. The Department of Health and Human Services ("DHHS") states that NDMA is

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[5] U.S. Environmental Protection Agency, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ ndma_fact_sheet_update_9-15-17_508.pdf.

[6] Jane Brody, *Bottoms Up: Alcohol in Moderation Can Extend Life*, The Globe & Mail (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger Grows as Officials Unable to Trace Poison in Reserve's Water*, The Globe & Mail (CANADA) (Jan. 6, 1990) (reporting that residents of SixNations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); Kyrtopoulos et al, *DNA Adducts in Humans After Exposure to Methylating Agents*, 405 Mut. Res. 135 (1998) (noting that "chronic exposure of ratsto very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

[7] *See* EPA Technical Fact Sheet, *supra* note 10; Int'l Agency for Research on Cancer (IARC), *Summaries & Evaluations, N-NITROSODIMETHYLAMINE* (1978), http://www.inchem.org/ documents/iarc/vol17/n-nitrosodimethylamine.html.

[8] 17 Int'l Agency for Research on Cancer, *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Some N-Nitroso Compounds* 151–52 (May 1978)

[9] *See* EPA Technical Fact Sheet, *supra* note 10.

reasonably anticipated to be a human carcinogen.[10] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[11]

69. The FDA considers NDMA a chemical that "could cause cancer" in humans.[12]

70. The World Health Organization states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[13]

71. As early as 1980, consumer products containing unsafe levels of NDMA and othernitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

72. Since the beginning of the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure—Valsartan, Losartan, and Irbesartan—because the medications contained nitrosamine impurities that do not meet the FDA's safety standards.

73. The no-observed-adverse-effect level ("NOAEL") is the level of exposure at which there is no biologically significant increase in the frequency or severity of any adverse effects of the chemical. Due to NDMA's ability to affect DNA at a microscopic level, there is no NOAEL for NDMA. This means any amount of NDMA exposure increases risk.

74. The FDA has set an acceptable daily intake ("ADI") level for NDMA at 96ng. That means that consumption of 96ng of NDMA a day would increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above 96ng is considered unacceptable.[14] Tobacco smoke also contains NDMA, with one filtered cigarette containing between 5ng to 43ng.

75. In studies examining carcinogenicity through oral administration, mice exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster studies,

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[10] *Id.* at 3.
[11] *Id.*
[12] FDA Statement, Janet Woodcock, Director – Ctr. for Drug Evaluation & Research, *Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine* (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting- patients-and-health-care-professionals-ndma-found-samples-ranitidine.
[13] World Health Org., *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3d ed. 2008), https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_ 2ndadd.pdf.
[14] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)* (Feb. 28, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

cancers were observed in the liver, pancreas, and stomach. In comparable guinea-pig studies, cancers were observed in the liver and lung. In comparable rabbit studies, cancers were observed in the liver and lung.

76. In other long-term animal studies in mice and rats utilizing different routes of exposures—inhalation, subcutaneous injection, and intraperitoneal (abdomen injection)—cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

77. Prior to the withdrawal of ranitidine, the FDA considered the drug as category B for birth defects, meaning it was considered safe to take during pregnancy. Yet animals exposed to NDMA during pregnancy birthed offspring with elevated rates of cancer in the liver and kidneys.

78. NDMA is a very small molecule. That allows it to freely pass through all areas of the body, including the blood-brain and placental barrier. This is particularly concerning as ranitidine has been marketed for pregnant women and young children for years.

79. In addition, NDMA breaks down into various derivative molecules that, themselves, are associated with causing cancer. In animal studies, derivatives of NDMA induced cancer in the stomach and intestine (including colon).

80. Research shows that lower levels of NDMA, *e.g.*, 40 ng, are fully metabolized in the liver, but high doses enter the body's general circulation.

81. Exposure to high levels of NDMA has been linked to liver damage in humans.[15]

82. Numerous *in vitro* studies confirm that NDMA is a mutagen—causing mutations in human and animal cells.

83. Overall, the animal data demonstrates that NDMA is carcinogenic in all animal species tested: mice; rats; Syrian golden, Chinese and European hamsters; guinea pigs; rabbits; ducks; mastomys; fish; newts; and frogs.

84. The EPA classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[16]

85. Pursuant to EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[17]

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[15] *See* EPA Technical Fact Sheet, *supra* note 10.
[16] *Id.*
[17] *See* U.S. Envtl. Protection Agency, Risk Assessment Forum, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.

86. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. And, while these studies consistently show increased risks of various cancers, the exposure levels considered in these studies are a very small fraction of the exposures noted in a single ranitidine capsule.

87. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 ng/day.[18]

88. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 ng/day.[19]

89. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at .179 ng/day.[20]

90. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "*N*-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[21]

91. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, pharynx, prostate, and brain cancer.[22]

92. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal

[18] Pobel et al., *Nitrosamine, Nitrate and Nitrite in Relation to Gastric Cancer: A Case-controlStudy in Marseille, France*, 11 Eur. J. Epidemiol. 67–73 (1995).
[19] La Vecchia, *et al*., *Nitrosamine Intake & Gastric Cancer Risk*, 4 Eur. J. Cancer. Prev. 469–74(1995).
[20] Rogers et al., *Consumption of Nitrate, Nitrite, and Nitrosodimethylamine and the Risk of UpperAerodigestive Tract Cancer*, 5 Cancer Epidemiol. Biomarkers Prev. 29–36 (1995).
[21] Knekt et al., *Risk of Colorectal and Other Gastro-Intestinal Cancers after Exposure to Nitrate,Nitrite and N-nitroso Compounds: A Follow-Up Study*, 80 Int. J. Cancer 852–56 (1999).
[22] Straif et al., *Exposure to High Concentrations of Nitrosamines and Cancer Mortality Among aCohort of Rubber Workers*, 57 Occup. Envtl. Med 180–87 (2000).

cancers.[23]

93. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.[24]

94. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant (*i.e.* not malignant) cancers, (2) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (3) reduce the ability of the body to combat cancer. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

95. NDMA is also known to be genotoxic, meaning it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro*. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the carcinogenicity of NDMA."[25]

III. NDMA IS DISCOVERED IN RANITIDINE-CONTAINING PRODUCTS, LEADING TO MARKET WITHDRAWAL

96. On September 9, 2019, pharmacy, and testing laboratory Valisure LLC and Valisure RX LLC (collectively, "Valisure") filed a Citizen Petition calling for the recall of all ranitidine-containing products due to exceedingly high levels of NDMA found in ranitidine pills. FDA and European regulators started reviewing the safety of ranitidine with specific focus on the presence of NDMA.[26] This set off a cascade of recalls by the Brand-Name Manufacturer, Retailer, and Repackager Defendants.

97. On September 13, 2019, the FDA's Director for Drug Evaluation and Research, Dr. Janet Woodcock, issued a statement warning that some ranitidine medicines may contain NDMA.[27]

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[23] Loh et al., *N-nitroso Compounds and Cancer Incidence: The European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 Am. J. Clinical Nutrition 1053–61 (2011).
[24] Zhu et al., *Dietary N-nitroso Compounds and Risk of Colorectal Cancer: A Case-control Study in Newfoundland and Labrador and Ontario, Canada*, 111 Brit. J. Nutrition 6, 1109–17 (2014).
[25] World Health Org., *supra* note 18.
[26] FDA Statement, Woodcock, *supra* note 17; Press Release, European Medicines Agency, *EMA to Review Ranitidine Medicines Following Detection of NDMA* (Sept. 13, 2019), https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection- ndma.
[27] FDA Statement, Woodcock, *supra* note 17.

98. On September 26, 2019, Retailer Defendant Walmart voluntarily recalled all ranitidine products and removed them from shelves.[28]

99. On October 2, 2019, the FDA ordered manufacturers of ranitidine to test their products and recommended using a liquid chromatography with high resolution mass spectrometer ("LC-HRMS") testing protocol, which "does not use elevated temperature."[29]

100. On October 8, 2019, Brand-Name Manufacturer Defendant GSK voluntarily recalled all ranitidine-containing products internationally.[30] As part of the recall, GSK publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac and noted that "GSKis continuing with investigations into the potential source of the NDMA."[31]

101. On October 18 and 23, 2019, Brand-Name Manufacturer Defendant Sanofi voluntarily recalled all of their ranitidine-containing products.[32]

102. On November 1, 2019, the FDA announced the results of recent testing, finding "unacceptable levels" of NDMA in ranitidine-containing products, and requested that drug makers begin to voluntarily recall their ranitidine-containing products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.[33]

103. On December 4, 2019, the FDA issued a statement notifying consumers who wished to continue taking ranitidine to consider limiting their intake of nitrite-containing foods, *e.g.*, processed meats and preservatives like sodium nitrite.[34] This advice ***mirrored*** an admonition issued by Italian scientists in 1981 after finding that ranitidine reacted with nitrites *in vitro* to form toxic and mutagenic effects in bacteria. The prudent advice of Dr. de Flora published in October 1981 in *The Lancet* was to "avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals or by giving inhibitors of nitrosation such as ascorbid acid."[35] If

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[28] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Sept. 26, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda- updates-and-press-announcements-ndma-zantac-ranitidine.

[29] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[30] Press Release, Gov. UK, *Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls All Unexpired Stock* (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock.

[31] Justin George Varghese, *GSK Recalls Popular Heartburn Drug Zantac Globally After Cancer Scare*, Reuters (Oct. 8, 2019), https://www.reuters.com/article/us-gsk-heartburn-zantac/gsk- recalls-popular-heartburn-drug-zantac-globally-after-cancer-scare-idUSKBN1WN1SL.

[32] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 23, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda- updates-and-press-announcements-ndma-zantac-ranitidine.

[33] U.S. Food & Drug Admin., Laboratory Tests | Ranitidine, https://www.fda.gov/drugs/drug- safety-and-availability/laboratory-tests-ranitidine (content current as of Nov. 1, 2019).

[34] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Dec. 4, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[35] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, The Lancet, Oct. 31, 1981, at 993–94.

GSK had only heeded Dr. de Flora's advice in 1981, millions of people might have avoided exposure to a known carcinogen and increased risk of developing cancer from ingesting ranitidine.

104. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that NDMA accumulates in ranitidine at unsafe rates when exposed to label-compliant temperature ranges that would occur during normal transport and storage conditions.

105. Emery's Citizen Petition outlined its substantial concern that ranitidine is a time- and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine in temperature-controlled vehicles.

106. In response,[36] on April 1, 2020, the FDA recounted that a recall is an "effective methods [sic.] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health."[37] The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury."[38] The FDA found that the recall of all ranitidine-containing products and a public warning of the recall was necessary because the "product being recalled presents a serious health risk."[39] The FDA therefore sent Information Requests to all applicants and pending applicants of ranitidine-containing products "requesting a market withdrawal."[40]

107. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine-containing products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed NDMA levels were higher as the products approached their expiration dates. The FDA's testing eroded the agency's confidence that any ranitidine-containing product could remain stable through its labeled expiration date. Consequently, the FDA withdrew the products from the market. The FDA's decision to withdraw the drug rendered moot Emery's request for temperature-controlled shipping conditions.

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[36] Letter of Janet Woodcock, U.S. Food & Drug Admin., Docket No. FDA-2020-P-0042 (Apr. 1, 2020), *available at* https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042- CP-Response-4-1-2020.pdf.
[37] *Id.* at 5 (*citing* 21 CFR 7.40(a)).
[38] *Id.*
[39] *Id.* at 7.
[40] *Id.* at 10 n.43.

108. The FDA's reaction was consistent with comparable regulatory action throughout the world. Before the FDA acted, over 43 different countries and jurisdictions restricted or banned ranitidine-containing products.[41]

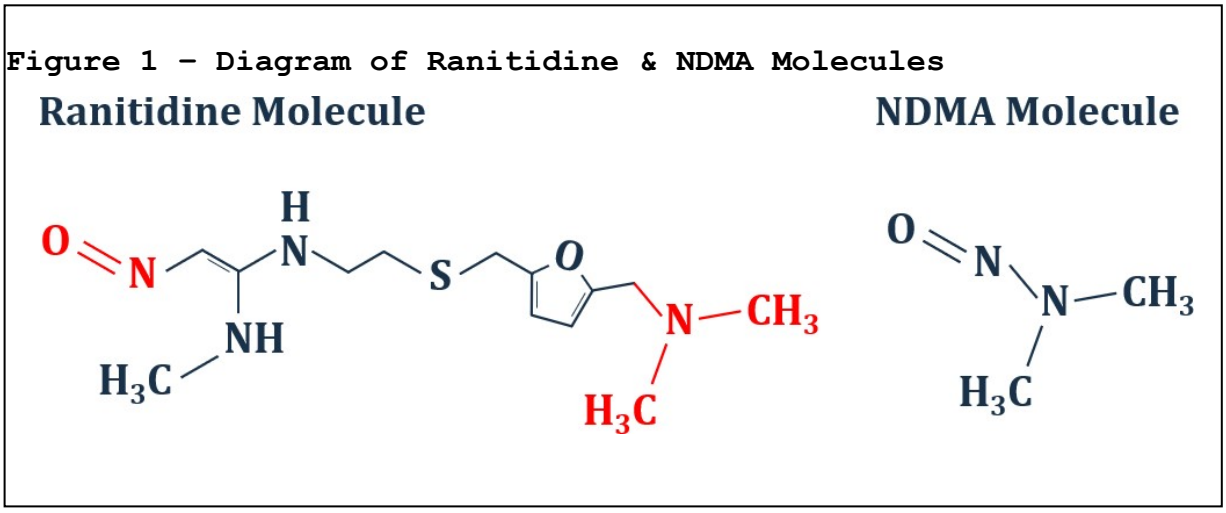
109. The European Medicines Agency ("EMA"), the European Union's equivalent to the FDA, through an Article 31 Referral, determined the sale of all ranitidine-containing products should be suspended on September 19, 2019. On April 30, 2020, the Human Medicines Committee of the EMA "has recommended the suspension of all ranitidine medicines in the EU due to the presence of low levels of an impurity called N-nitrosodimethylamine (NDMA)." The EMA recognizes NDMA as a probable human carcinogen and issued a "precautionary suspension of these medicines in the EU" because "NDMA has been found in several ranitidine medicines above levels considered acceptable, and there are unresolved questions about the source of the impurities."[42]

IV. HOW RANITIDINE TRANSFORMS INTO NDMA

110. The ranitidine molecule itself contains the constituent molecules to form NDMA. *See* Figure 1.

111. Specifically, the O=N (Nitroso) on one side of the ranitidine molecule can combine with the H_3C-N-CH_3 (DMA) on the other side to form NDMA.

Figure 1 – Diagram of Ranitidine & NDMA Molecules



112. The formation of NDMA by the reaction of DMA and a nitroso source (such as a

[41] Margaret Newkirk & Susan Berfield, *FDA Recalls Are Always Voluntary and Sometimes Haphazard—and The Agency Doesn't Want More Authority to Protect Consumers*, Bloomberg Businessweek (Dec. 3, 2019), https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/.

[42] Ogawa et al., *Purification and Properties of a New Enzyme, NG, NG-dimethylarginine Dimethylaminohydrolase, from Rat Kidney*, 264 J. Bio. Chem. 17, 10205–209 (1989).

nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the U.S. water supply.[43] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater-treatment plants was specifically linked to the presence of ranitidine.[44]

113. Ranitidine leads to NDMA exposure in four ways: (1) formation of NDMA in the human digestive system; (2) formation of NDMA due to an enzymatic reaction throughout the human body; (3) formation of NDMA over time under normal storage conditions and which increases significantly when exposed to heat; and (4) formation of NDMA during the manufacturing process.

A. Formation of NDMA in the Environment of the Human Stomach

114. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule (0=N) and the DMA molecule (H3C-N-CH3) break off and reform as NDMA.

115. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, *The Lancet*. When ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects."[45] Dr. de Flora hypothesized that these mutagenic effects could have been caused by the "formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions." *Id.* Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent to … suggest a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals."[46]

116. GSK knew of Dr. de Flora's publication because, two weeks later, GSK responded in *The Lancet*, claiming that the levels of nitrite needed to induce the production of nitroso derivatives (*i.e.*, NDMA) were not likely to be experienced by people in the real world.[47]

117. This response reflects GSK's reputation for "adopting the most combative,

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[43] Mitch et al., *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20Env. Eng. Sci. 5, 389–404 (2003).
[44] *Id*.
[45] De Flora, *supra* note 45.
[46] This admonition came two years before the FDA approved Zantac in 1983. Notwithstanding, in 1998 GSK applied for and obtained an indication for OTC Zantac "[f]or the prevention of meal-induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal." *See* Ctr. for Drug Eval. & Research, *Approval Package* (June 8, 1998), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20520s1_Zantac.pdf. So GSK specifically invited patients to take Zantac shortly before eating heartburn-inducing food.
[47] R. T., Brittain et al., *Safety of Ranitidine*, *The Lancet* 1119 (Nov. 14, 1981).

scorched-earth positions in defense of its brands."[48] The company has no compunctions against distorting objective science to maintain its lucrative monopoly franchises, and its egregious conduct surrounding Zantac is not some isolated incident.

118. GSK endangered patient health while reaping billions of dollars in profits from Paxil, Wellbutrin, and Avandia. As we now know, the company was involved in covering up scientific data, offering illegal kickbacks to prescribing physicians, intimidating witnesses, and defrauding Medicare to profit from these medicines. In the wake of Congressional hearings into the company's outrageous misbehavior,[49] GSK's actions resulted in a criminal investigation and the then-largest guilty plea by a pharmaceutical company for fraud and failure to report safety datain the country's history.[50]

119. In its submission to the FDA, GSK explained that the level of nitrite present would be unrealistic and, thus, these results had no "practical clinical significance"[51]

> Although N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as an unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

120. Around this same time—before Zantac was approved by the FDA—GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach.[52] Remarkably, in the study that was presented to the FDA, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of developing NDMA and, in turn, cancer, but then dismissed this risk because people were allegedly only expected to

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[48] Jim Edwards, *GSK's Alleged Coverup of Bad Avandia Data: A Snapshot of Its Poisonous Corporate Culture*, Moneywatch (July 13, 2010) https://www.cbsnews.com/news/gsks-alleged-coverup-of-bad-avandia-data-a-snapshot-of-its-poisonous-corporate-culture/.

[49] *Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia*, Senate Comm. on Finance,111th Cong.2d Sess. 1 (Comm. Print Jan. 2010).

[50] U.S. Dep't of Justice, *GlaxoSmithKline to Please Guilty and Pay $3 Billion to Resolve FraudAllegations and Failure to Report Safety Data* (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud- allegations-and-failure-report.

[51] Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac in the early 1980s. This document was obtained through a Freedom of Information Act request to the FDA.

[52] The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.

use ranitidine-containing products for a short-term period:

> The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

121. GSK knew—and indeed specifically admitted—that ranitidine could react with nitrite in the human stomach to form NDMA and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach.

122. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients.[53] The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. The study, however, was rigged. It did not use gold-standard mass spectrometry to test for NDMA, but instead, used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded."[54] In other words, GSK intentionally rigged the study to exclude the very samples most likely to contain a dangerous carcinogen.

123. In 1983, the same year Zantac obtained approval from the FDA, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm DNA).[55] The researchers concluded "it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells."

124. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings.[56] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine." Again, the authors noted that, "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the

[53] Thomas et al., *Effects of One Year's Treatment with Ranitidine and of Truncal Vagotomy onGastric Contents*, 6 Gut. Vol. 28, 726–38 (1987).
[54] *Id*.
[55] Maura et al., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18Tox. Lttrs. 97–102 (1983).
[56] De Flora et al., *Genotoxicity of Nitrosated Ranitidine*, 4 Carcinogenesis 3, 255–60 (1983).

prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals." This admonition carries weight considering GSK's studies indicate that long-term ranitidine consumption, itself, leads to elevated levels of nitrites in the human gut.

125. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.[57] These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water-treatment plants that supply many U.S. cities with water.

126. In 2016, researchers at Stanford University conducted an experiment on healthy volunteers.[58] They measured the NDMA in urine of healthy individuals over the course of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same individuals for another 24 hours. On average, the level of NDMA increased by 400 times, to approximately 47,000 ng. The only change during that 24-hour period was the consumption of ranitidine. This study directly demonstrates that unsafe levels of NDMA are formed in the human body as a result of ranitidine ingestion. The scientists further explained that previous studies have indicated a high metabolic conversion rate of NDMA, meaning it will be processed by the human body. As such the observed 47,000 ng likely only captured 1/100 of the actual NDMA levels in the human body.

127. These studies did not appreciate the full extent of NDMA formation risk from ranitidine; specifically, the added danger of this drug having not only a labile DMA group but also a readily available nitroso source in its nitrite group on the opposite terminus of the molecule. Recent testing of NDMA levels in ranitidine batches are so high that the nitroso for NDMA likely comes from no other source than the ranitidine molecule itself.

128. Valisure is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO")—an accreditation recognizing the laboratories technical competence for regulatory purposes. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications,

[57] Le Roux et al., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*,46 Envtl. Sci. Tech. 20, 11095–103 (2012).
[58] Zeng et al., *Oral intake of Ranitidine Increases Urinary Excretion of N-nitrosodimethylamine*,37 Carcinogenesis 625–34 (2016).

generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

129. In its September 9, 2019, Citizen's Petition to the FDA,[59] Valisure disclosed as part of its testing of ranitidine-containing products that in every lot tested there were exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.[60] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol

150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**
Reference Powder	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

130. Valisure's testing shows, on average, 2,692,291 ng of NDMA in a 150 mg ranitidine tablet. This testing demonstrates the instability of the ranitidine molecule and its propensity to break down under higher temperatures and in a high nitrite environment, such as in the human stomach.

[59] Valisure, *Citizen Petition on Ranitidine* (Sept. 9, 2019), *available at* https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf

[60] U.S. Food & Drug Admin., *Combined N-Nitrosodimethlyamine (NDMA) and N- Nitrosodiethylamine (NDEA) Impurity Assay, FY19-005-DPA-S* (Jan. 28, 2019).

131. Valisure was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130°C in the FDA recommended GC/MS protocol. So Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37°C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

132. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF": 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF": 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs. The inclusion of nitrite in gastric fluid testing is commonplace and helps simulate the environment of a human stomach.

133. Indeed, ranitidine-containing products were specifically advertised to be used when consuming foods containing high levels of nitrates, such as tacos or pizza.[61]

134. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present (*see* Table 2).

Table 2 – Valisure Biologically Relevant Tests for NDMA Formation

Ranitidine Tablet Studies	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid ("SIF")	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

[61] *See, e.g* Zantac television commercial, *Family Taco Night*, https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; Zantac television commercial, *Spicy*, https://youtu.be/jzS2kuB5_wg; Zantac television commercial, *Heartburn,* https://youtu.be/Z3QMwkSUlEg; Zantac television commercial, *Zantac Heartburn Challenge*, https://youtu.be/qvh9gyWqQns.

135. Under biologically relevant conditions, when nitrites are present, high levels of NDMA are found in one dose of 150 mg ranitidine, ranging between 245 and 3,100 times above the FDA-allowable limit. One would need to smoke over 500 cigarettes to achieve the same levelsof NDMA found in one dose of 150 mg ranitidine at the 25 nanogram level (over 7,000 for the 50nanogram level).

136. Following the release of Valisure Citizen's Petition, the FDA conducted additional laboratory tests, which showed NDMA levels in all ranitidine samples it tested, including API and the finished drug, both tablets and syrup. The FDA developed simulated gastric fluid ("SGF") andsimulated intestinal fluid ("SIF") models to use with the LC-MS testing method to estimate the biological significance of *in vitro* findings. These models are intended to detect the formation of NDMA in systems that approximate the stomach and intestine. The testing showed unacceptable levels of NDMA.

137. When the scientific data is assessed overall, the literature demonstrates that the ingestion of ranitidine in the presence of human-relevant levels of nitrite in the stomach—a substance that is commonly found in foods that induce heartburn and that is known to be elevated in people taking ranitidine for longer than a month—the ranitidine molecule breaks down into levels of NDMA that would dramatically increase a person's risk of developing cancer.

B. Formation of NDMA in Other Organs of the Human Body

138. In addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues and organs separate from the stomach.

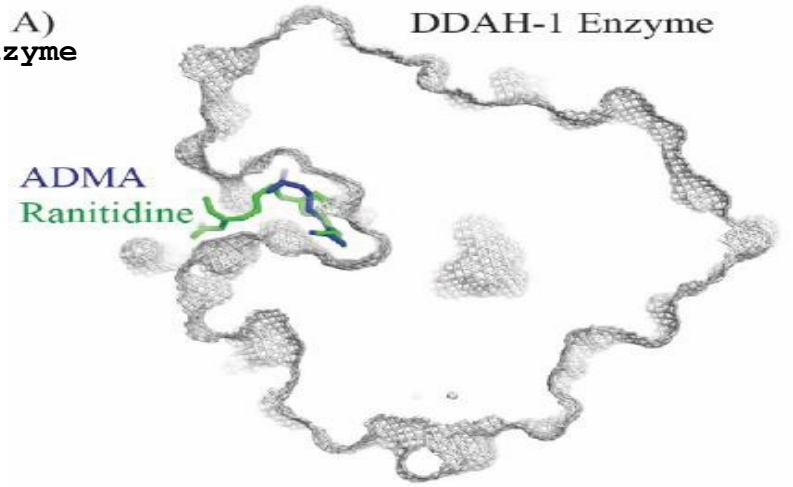
139. Liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a

potent carcinogen, dimethylnitrosamine [NDMA]."[62]

140. In Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA," shown in blue).

[62] Ogawa, *et al*., *supra* note 54.

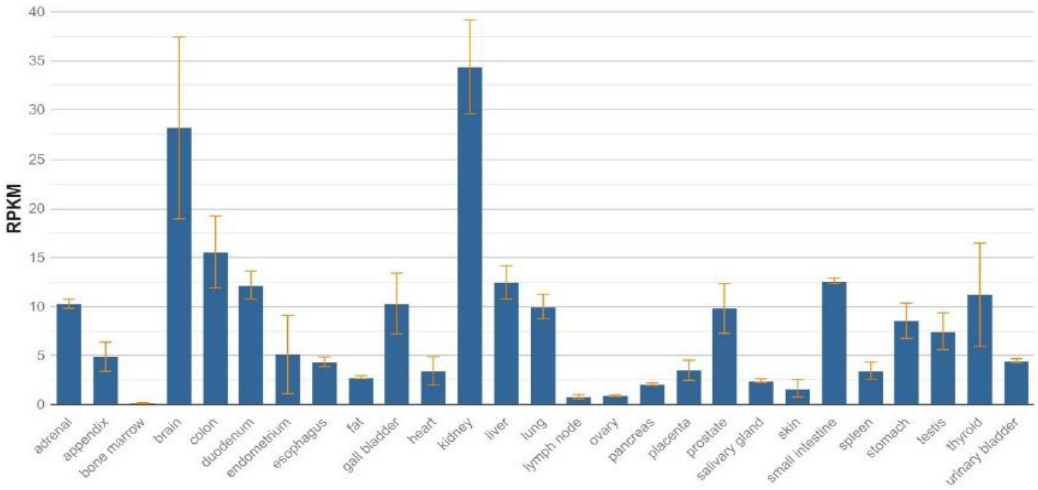
Figure 2 – Computational Modelling of Ranitidine Binding to DDAH-1 Enzyme



B)

	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
Ranitidine	-6.1 ± 0.1

Figure 3 – Expression levels of DDAH-1 enzyme by Organ



141. These results indicate that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

142. Figure 3 above, derived from the National Center for Biotechnology Information, illustrates the expression of the DDAH-1 gene in various tissues in the human body.

143. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the brain, colon, liver, small intestine, stomach, bladder, and prostate. This offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs.

144. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body. Indeed, ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1-2 hours. When ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA. This observation is validated by the Stanford study, discussed above.

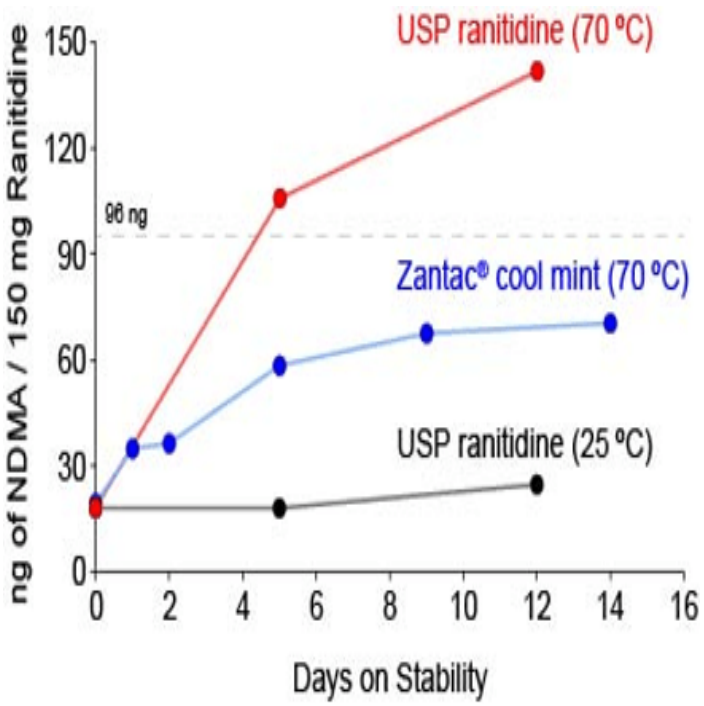
C. Formation of NDMA by Exposure to Heat and/or Time

145. The risk of creating NDMA by exposing ranitidine to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that NDMA formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which initially used a high-heat testing method but also specifically developed a detection protocol that did not use heat.

146. In response to Valisure, on October 2, 2019, the FDA recommended that researchers use the LC-HRMS protocol for detecting NDMA in ranitidine because the "testing method does not use elevated temperatures" and has been proven capable of detecting NDMA.

147. On January 2, 2020, Emery Pharma, an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine. The researchers exposed ranitidine to 70 ˚C for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. The following diagram reveals how NDMA accumulates over time when exposed to 70 ˚C:

Figure 4 – Rate of Development of NDMA when Exposed to Heat



148. The researchers cautioned:

> NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, which would be routinely reached during shipment and during storage. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer.[63]

149. The results of this data demonstrate that in normal transport and storage, and especially when exposed to heat, the ranitidine molecule systematically breaks down into NDMA, accumulating over time in the finished product. Considering ranitidine-containing products have an approved shelf life of 36 months, the possibility of the drug accumulating dangerously high levels of NDMA prior to consumption is very real—a point underscored by the FDA's swift removal of the product from the market.

150. In fact, the FDA acknowledged that testing revealed that NDMA levels in

[63] Emery Pharma, *Emery Pharma Ranitidine: FDA Citizen Petition* (Jan. 7, 2020), *available at* https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/.

ranitidine products stored at room temperature can increase with time to unacceptable levels and elevated levels of NDMA were measured in *all products after 2 weeks*.[64]

D. Formation of NDMA in the Manufacturing Process

151. Recent testing conducted under the auspices of the FDA involving a number of drugs within the last two years also demonstrates that NDMA can form during the manufacturing process.

152. On July 13, 2018, the FDA announced the first of what would be many recalls of Valsartan and other angiotensin receptor blocker ("ARB") drugs used to treat high blood pressure, such as losartan and irbesartan.[65]

153. Specifically, the recalls were due to NDMA and other nitrosamines being present in the APIs manufactured by four API manufacturers located in China and India.

154. According to the Council on Foreign Relations, "approximately 80% of the active pharmaceutical ingredients (APIs) used to make drugs in the United States are said to come from China and other countries like India."[66]

155. As the FDA's investigation into the ARB contamination continued, it became clear that NDMA had made its way into the API through the use of recovered solvents or as a result of using less expensive solvents during the manufacturing process.[67] Similarly, API was noted as a possible source of NDMA in ranitidine-containing drugs: "Lannett was notified by FDA of the potential presence of NDMA on September 17, 2019 and immediately commenced testing of the Active Pharmaceutical Ingredient (API) and drug product. The analysis confirmed the presence of NDMA."[68]

156. FDA's early testing of ranitidine was conducted without utilizing heat and without subjecting the pills to gastric conditions. This testing nonetheless revealed unacceptable

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[64] Woodcock Letter, *supra* note 47.

[65] FDA News Release, U.S. Food & Drug Admin., *FDA Announces Voluntary Recall of SeveralMedicines Containing Valsartan Following Detection of an Impurity U.S. Food and Drug Administration* (July 13, 2018), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity.

[66] Yanzhong Huang, *U.S. Dependence on Pharmaceutical Products from China* (Aug. 14, 2019), https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china.

[67] Press Announcements, U.S. Food & Drug Admin., *FDA Updates & Press on ARB Recalls: Valsartan, Losartan and Irbesartan U.S. Food and Drug Administration* (Nov. 13, 2019). https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements- angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

[68] Company Announcement, Lannett, *supra* note 42.

levels of NDMA.[69]

V. EVIDENCE DIRECTLY LINKS RANITIDINE EXPOSURE TO CANCER

157. In addition to numerous epidemiology studies examining how NDMA causes cancer in humans, researchers have also specifically looked at ranitidine and found an association with cancer.

158. One epidemiology study, published in 2004, showed that men taking either ranitidine or cimetidine (Tagamet) had increased risks of bladder cancer.[70]

159. In one epidemiology study specifically designed to look at breast cancer, ranitidine was shown to more than double the risk, an effect that was even more pronounced in those with specific gene mutations.[71]

160. In another comprehensive epidemiological study looking at various cancer risks and histamine H2-receptor antagonists (or H2 blockers), including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer.[72] Of particular note, the study indicated that people under the age of 60 who took ranitidine were five times more likely to develop prostate cancer. In addition, there was more than a doubling the risk of pancreatic cancer with ranitidine use.

161. A study published in 2018, demonstrated an increased risk of liver cancer associated with use of ranitidine in comparison with other H2 blockers in the class. The purpose of the study was to determine whether there was an increased risk of liver cancer associated with proton pump inhibitors, a different class of medications indicated for the treatment of GERD. This finding is particularly notable as the authors adjusted for variables.[73]

162. In 2018, a study found an increased risk in hepatocellular carcinoma associated with use of H2 blockers.[74] The authors were evaluating the risk of cancer in association with proton pump inhibitors and looked at H2 blockers as a confounder. The study only considered use of H2 blockers within one year of cancer diagnosis and still found an increased odds ratio

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[69] Press Announcements, U.S. Food & Drug Admin., *NDMA in Zantac (ranitidine)* (Oct. 2, 2019),https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements- ndma-zantac-ranitidine.

[70] D. Michaud et al., *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 Cancer Epi. Biomarkers & Prevention 250–54 (Feb. 2004).

[71] Robert W. Mathes et al., *Relationship Between Histvamine2-receptor Antagonist Medications and Risk of Invasive Breast Cancer*, 17 Cancer Epi. Biomarkers & Pevention 1, 67–72 (2008).

[72] Laurel A Habel et al., *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 Pharmacoepidemiology & Drug Safety 149–55 (2000).

[73] Kim Tu Tran et al., *Proton Pump Inhibitor and Histamine-2 receptor Antagonist Use and Risk of Liver Cancer in Two Population-based Studies*, 48 Alimentary Pharmacology & Therapeutics1, 55–64 (2018).

[74] Y-H J Shao et al., *Association Between Proton Pump Inhibitors and the Risk of Hepatocellular Carcinoma*, 48 Alimentary Pharmacology & Therapeutics 4, 460–68 (2018).

associated with use of H_2 blockers and hepatocellular carcinoma, a type of liver cancer.

163. A number of other studies have been published over the years showing an increased risk of various cancers associated with use of ranitidine and/or H_2 blockers.[75] These cancers include breast, gastric, pancreatic, and stomach cancer. Additional research reports that ranitidine use was associated with a significant increase in the risk of breast, testicular, thyroid, and kidney cancer.[76]

VI. DEFENDANTS KNEW OR SHOULD HAVE KNOWN OF THE NDMA RISK

164. As early as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA, when properly tested.[77] This was known or should have been known by the Brand-Name Manufacturer Defendants and Repackager Defendants ("Knowledge Defendants") or any other manufacturer or distributor of ranitidine-containing products as the information was available in medical literature. Such literature should have been accessed by all companies in the chain of distribution of ranitidine, even if it would have been difficult to locate for a regular consumer.

165. In 1981, GSK, the originator of the ranitidine molecule, published a study focusing on the metabolites of ranitidine in urine using liquid chromatography.[78] Many metabolites were listed, though there is no indication that the study looked for NDMA.

166. Indeed, in that same year, Dr. de Flora published a note discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites—a substance commonly found in food and in the body.[79] GSK was aware of this study because GSK specifically responded to the note and attempted to discredit it. Knowledge Defendants knew or should have known about this scientific exchange as it was published in a popular scientific journal. Knowledge Defendantswere obligated to investigate this issue properly. None did.

167. By 1987, after numerous studies raised concerns over ranitidine and cancerous

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[75] Mathes et al., *supra* note 82; *see also* Jeong Soo Ahn et al., *Acid Suppressive Drugs and Gastric Cancer: A Meta-analysis of Observational Studies*, 19 World J. Gastroenterology 16, 2560 (2013); Shih-Wei Lai et al., *Use of Proton Pump Inhibitors Correlates with Increased Risk of Pancreatic Cancer: A Case-control Study in Taiwan*, 46 Kuwait Med J. 1, 44–48 (2014); Poulsen et al., *Proton Pump Inhibitors and Risk of Gastric Cancer – A Population Based Cohort Study*, 100 Brit. J. Cancer 1503–07 (2009); E Wennerström, *Acid-suppressing Therapies and Subsite- specific Risk of Stomach Cancer*, 116 Brit. J. Cancer 9, 1234–38 (2017).

[76] Richard H. Adamson & Bruce A. Chabne, *The Finding of N-Nitrosodimethylamine in CommonMedicines,* The Oncologist, June 2020; 25(6): 460–62, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7288647/.

[77] *See supra* ¶ 311 (discussing de Flora research).

[78] Carey et al., *Determination of Ranitidine and Its Metabolites in Human Urine by Reversed- phase Ion-pair High-performance Liquid Chromatography*, 255 J. Chromatography B: Biomedical Sci. & Appl. 1, 161–68 (1981).

[79] De Flora, *supra* note 45.

nitroso compounds (discussed previously in Factual Allegations, Section IV), GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[80] That study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was rigged. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Not only is that approach not accurate, but GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. The inadequacy of that test was knowable in light of its scientific publication in 1987. All Defendants either knew or should have known about the inadequacy of that study and should have investigated the issue properly and/or took action to protect consumers from the NDMA risks in their products. None did.

168. In fact, upon information and belief, no Defendant ever used a mass spectrometry assay to test for the presence of nitrosamines in any of the studies and trials they did in connection with their trials associated with the ranitidine NDA. That is because mass spectrometry requires heating of up to 130 degrees Celsius, which can result in the formation of excessive amounts of nitrosamines. Had the Brand-Name Manufacturer and Generic Manufacturer Defendants used a mass spectrometry assay, it would have revealed large amounts of NDMA.

169. There are multiple alternatives to ranitidine that do not cause cancer, and the benefits of using ranitidine were always outweighed by the risk-adjusted costs.

THE FEDERAL REGULATORY LANDSCAPE

170. Plaintiff referenced federal law herein not in any attempt to enforce it, but only to demonstrate that his state-law tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

I. BRAND-NAME MANUFACTURER DEFENDANTS MADE FALSE STATEMENTS IN THE LABELING OF RANITIDINE-CONTAINING PRODUCTS

171. A manufacturer is required to give adequate directions for the use of a

[80] Thomas et al., *supra* note 61.

pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[81] and conform to requirements governing the appearance of the label.[82]

172. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[83] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

173. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as/ including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[84]

174. All drug manufacturers (brand and generic) are also responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products."[85] Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."[86]

175. The purpose of stability testing is, in part, to determine "the appropriate storage conditions and expiration dates."[87] And expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use."[88] An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in § 211.166."[89]

176. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and

[81] 21 C.F.R. § 201.5.
[82] *Id.* § 201.15.
[83] *Id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000).
[84] *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[85] 21 C.F.R. § 211.166(a).
[86] *Id.*
[87] *Id.*
[88] *Id.* § 211.137(a).
[89] *Id.* § 211.137(b).

inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."[90]

177. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf-life studies, there must be stability studies conducted . . . until the tentative expiration date is verified, or the appropriate expiration date determined."[91]

178. After a drug is approved, a manufacturer (brand or generic) can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§ 314.70 and 314.71.[92]

179. Some of the requirements in those regulations require a brand or generic manufacturer of an approved drug to obtain FDA approval before implementing a label change.[93]

180. But the FDA has long recognized a "changes being effected" ("CBE") supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review.[94]

181. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess."[95] "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."[96]

182. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date—which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use"[97]—or to ensure that the drug is shipped and stored under appropriate conditions.

183. A manufacturer of an approved drug can also use the CBE supplement to make

[90] 43 Fed. Reg. 45059 (Sept. 29, 1978).
[91] 21 C.F.R. § 211.166(b).
[92] *See id.* §§ 314.70, 314.97(a) (requiring generics to comply).
[93] *Id.* § 314.70(b).
[94] *Id.* § 314.70(c)(3), (c)(6).
[95] *Id.* § 314.70(c)(6)(i).
[96] 65 Fed. Reg. 83042 (Dec. 29, 2000).
[97] 21 C.F.R. § 211.137(a).

changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use orclaims for effectiveness."[98]

184. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, thatdoes not involve a change in the dosage strength or dosage form."[99]

185. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf-life data on production batches obtained from a protocol approved in the NDA."[100]

186. At no time did any Brand-Name Manufacturer or Generic Manufacturer Defendant ("Manufacturer Defendants") attempt to include a warning about NDMA levels in ranitidine and its association with cancer, and the FDA never rejected such a warning. Manufacturer Defendants holding the NDAs had the ability to unilaterally add an NDMA and/or cancer warning to the labels of ranitidine-containing products (for both prescription and OTC) without prior FDA approval pursuant to the CBE regulation. Had any such Manufacturer Defendant attempted to add an NDMA warning to the label of its ranitidine-containing products (either for prescription or OTC),the FDA would not have rejected it.

187. At no time did any Manufacturer Defendant attempt to change its label to delete a false or misleading expiration date, to delete false or misleading shipping and storage conditions,to add a proper expiration date, or to add proper shipping and storage conditions, to ensure that ranitidine-containing products would not break down into NDMA prior to human consumption.

188. Based on the public scientific information available starting in 1983 (or earlier), the Manufacturer Defendants knew or should have known that NDMA could form in ranitidine

[98] *Id.* § 314.70(c)(6)(iii)(A), (C), (D).
[99] *Id.* § 314.70 (d)(2)(ix).
[100] *Id.* § 314.70 (d)(2)(vi).

by exposure to heat and/or over time in storage.

189. At no time did any Manufacturer Defendant change its label to shorten the expiration date or alter the safe shipping and storage conditions of its ranitidine-containing product, and the FDA never rejected such changes. Manufacturer Defendants had the ability to unilaterally make such label changes (for both prescription and OTC) without prior FDA approvalpursuant to the CBE regulation. Had any Manufacturer Defendant attempted such label changes,the FDA would not have rejected them.

190. Because they failed to warn that ranitidine-containing products contained NDMA, Manufacturer Defendants made false statements in the labeling of their products.

191. Because they failed to include appropriate expiration dates on their products, Manufacturer Defendants made false statements in the labeling of their products.

192. Because they failed to include proper storage instructions on their products, Manufacturer Defendants made false statements in the labeling of their products.

II. FEDERAL LAW REQUIRED THE MANUFACTURER DEFENDANTS TO NOTIFY THE FDA ABOUT THE PRESENCE OF NDMA IN RANITIDINE-CONTAINING PRODUCTS

193. During the time that Manufacturer Defendants manufactured and sold ranitidine-containing products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA. Manufacturer Defendants failed to disclose this risk to consumers on the drug's label—or through any other means—and they failed to report these risks to the FDA.

194. Manufacturer Defendants concealed the ranitidine–NDMA link from ordinary consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like ranitidine to the agency's attention.

195. Manufacturers (brand and generic) of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. § 314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

196. 21 C.F.R. § 314.81(b)(2)(v) provides:

> The manufacturer's annual report also must contain copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (*e.g.*, mutagenicity) conducted by, or otherwise obtained by, the[manufacturer] concerning the ingredients in the drug product.

197. Manufacturer Defendants ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in their products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of ranitidine-containing products.

198. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the publicly available scientific literature such that any manufacturer or distributor, consistent with their heightened obligations to ensure the safety of their products, also should have known about the potential NDMA risks associated with ranitidine consumption.

199. Manufacturer Defendants never conducted or provided the relevant studies to the FDA, nor did they present the FDA with a proposed disclosure noting the link between ranitidine and NDMA. Accordingly, because Manufacturer Defendants never properly disclosed the risk to the FDA, they never proposed any labeling or storage / transportation guidelines that would have addressed this risk. Thus, the FDA was never able to reject any proposed warning or proposal for transport / storage.

200. When the FDA eventually learned about the NDMA risks posed by ranitidine-containing products, it ordered manufacturers to voluntarily remove the products from the market. Thus, had any Manufacturer Defendant alerted the FDA to the risks of NDMA, the FDA would have required the manufacturers to remove ranitidine-containing products from the market.

III. CURRENT GOOD MANUFACTURING PRACTICES

201. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with "Current Good Manufacturing Practices" ("CGMPs") to ensure they meet safety, quality, purity, identity, and strength standards.[101]

202. 21 C.F.R. § 210.1(a) states that the CGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for,

[101] 21 U.S.C. § 351(a)(2)(B).

the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

203. Pursuant to 21 C.F.R. § 211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendants had a duty and were obligated to properly store, handle, and warehouse ranitidine.

204. Any drug not manufactured in accordance with CGMPs is deemed "adulterated and/or misbranded" and may not be distributed or sold in the United States.[102] State common law and statutory law mirror these federal standards.

205. Testing conducted by the FDA confirms that improper storage of ranitidine has resulted in extremely high levels of NDMA.[103] FDA has also concluded that NDMA can increase in ranitidine even under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in ranitidine-containing products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw ranitidine-containing products altogether.

206. Nothing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring cooled storage and transport. Such actions would not have required FDA approval, nor would they have violated any regulatory decisions or laws.

IV. RANITIDINE-CONTAINING PRODUCTS ARE MISBRANDED AND ADULTERATED BECAUSE THEY CONTAIN DANGEROUS AND BIOLOGICALLY RELEVANT LEVELS OF NDMA

207. The manufacture of any misbranded or adulterated drug is prohibited under

[102] *Id.* §§ 331(a), 351(a)(2)(B).
[103] Woodcock Letter, *supra* note 47.

federal law.[104]

208. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[105]

209. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[106]

210. Among the ways a drug may be adulterated and/or misbranded are:

1. "If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice . . . as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."[107]
2. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and . . . its quality or purity falls below, the standard set forth in such compendium"[108]
3. "If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor."[109]

211. A drug is misbranded:

a. "If its labeling is false or misleading in any particular."[110]
b. "If any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon . . . in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[111]
c. If the labeling does not contain, among other things, "the proportion of each active ingredient . . ."[112]
d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings . . . against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users"[113]
e. "If it purports to be a drug, the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."[114]

[104] 21 U.S.C. § 331(g).
[105] *Id.* § 331(a).
[106] *Id.* § 331(c).
[107] *Id.* § 351(a)(2)(B).
[108] *Id.* § 351(b).
[109] *Id.* § 351(d).
[110] *Id.* § 352(a)(1).
[111] *Id.* § 352(c).
[112] *Id.* § 352(e)(1)(A)(ii).
[113] *Id.* § 352(f).
[114] *Id.* § 352(g).

f. "If it is an imitation of another drug."[115]
g. "If it is offered for sale under the name of another drug."[116]
h. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[117]
i. If the drug is advertised incorrectly in any manner.[118]
j. If the drug's "packaging or labeling is in violation of an applicable regulation."[119]

212. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[120]

213. Because Defendants did not disclose NDMA as an ingredient in ranitidine-containing products ingested by Plaintiff, the subject drugs were misbranded.

214. Because Defendants did not disclose the proper directions for storage of the ranitidine-containing products ingested by Plaintiff, the subject drugs were misbranded.

215. Because Defendants did not disclose the proper directions for expiration of theranitidine-containing products ingested by Plaintiff, the subject drugs were misbranded

216. It is unlawful to introduce a misbranded drug into interstate commerce.[121] Thus,the ranitidine ingested by Plaintiff was unlawfully distributed and sold.

DEFENDANTS' WARRANTIES TO PLAINTIFF

I. WARRANTIES COMMON TO MANUFACTURER AND REPACKAGER DEFENDANTS.

217. Each Manufacturer and Repackager Defendant's ranitidine-containing product is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved label, Manufacturer and Repackager Defendants made representations and express or implied warranties to consumers like Plaintiff that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded.

218. In addition, each Manufacturer and Repackager Defendant affirmatively misrepresented and warranted to physicians and patients like Plaintiff through their websites, brochures, and other marketing or informational materials that their ranitidine-containing

[115] 21 U.S.C. § 352(i)(2).
[116] *Id.* § 352(i)(3).
[117] *Id.* § 352(j).
[118] *Id.* § 352(n).
[119] *Id.* § 352(p).
[120] *Id.* § 201.6, 201.10.
[121] *Id.* § 331(a).

products complied with CGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

219. The presence of NDMA in Manufacturer and Repackager Defendants' ranitidine-containing products resulted in Manufacturer and Repackager Defendants' ranitidine-containing products containing an ingredient that is not also listed on each Defendant's FDA-approved label, breaching warranties listed on each Defendant's FDA-approved label and Defendants' express warranty of compliance. Each Manufacturer and Repackager Defendant willfully, recklessly, or negligently failed to ensure their products' labels and other advertising or marketing statements accurately conveyed information about their products.

220. At all relevant times, Manufacturer and Repackager Defendants have also impliedly warranted that their ranitidine-containing products were merchantable and fit for their ordinary purposes.

221. Due to its status as a probable human carcinogen as listed by both the IARC and the EPA, NDMA is not an FDA-approved ingredient. The presence of NDMA in Manufacturer and Repackager Defendants' ranitidine-containing products means that Manufacturer and Repackager Defendants violated implied warranties to Plaintiffs. The presence of NDMA in Manufacturer and Repackager Defendants' products results in their being non-merchantable and not fit for their ordinary purposes, breaching Manufacturer and Repackager Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

222. For these and other reasons, Manufacturer and Repackager Defendants' ranitidine-containing products are adulterated and/or misbranded, and it was illegal for Brand-Name Manufacturer Defendants to have introduced such ranitidine into commerce in the United States.[122]

PLAINTIFF'S USE OF RANITIDINE-CONTAINING PRODUCTS

223. Plaintiff was prescribed and/or ingested ranitidine at various times as part of his treatment for gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

224. Plaintiff used ranitidine-containing products designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants. Those products, unbeknownst to Plaintiffs, contained dangerous levels of NDMA.

[122] *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

225. Plaintiff developed cancer as a result of consistently using ranitidine-containing products for approximately 3-5 years.

226. Plaintiff suffered significant bodily injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity and have and will incur past and future medical expenses.

227. Based on prevailing scientific evidence, exposure to ranitidine (and the attendant NDMA) causes cancer in humans.

228. At all relevant times, Knowledge Defendants knew or should have known that there was a significant increased risk of cancer associated with ranitidine, and death related to those diseases. Knowledge Defendants continued to design, manufacture, test, market, label, package, handle, distribute, store, and/or sell and profit from sales of ranitidine until it was withdrawn from the market.

229. Knowledge Defendants knowingly, purposely, and deliberately failed to warn Plaintiff, patients, consumers, medical providers, the FDA, and the public of the increased risk of serious injury associated with using ranitidine, and death related to those events.

230. Plaintiff's prescribing physicians would not have prescribed ranitidine to Plaintiff, would have changed the way in which they treated Plaintiff's relevant conditions, changed the way they warned Plaintiff about the signs and symptoms of serious adverse effects of ranitidine, and discussed with Plaintiff the true risks of cancer, had Knowledge Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of ranitidine-containing products.

231. Upon information and belief, Plaintiff's physicians were unaware of the increased risk of multiple types of cancer associated with the use of ranitidine and, if they had been informed,would have used and prescribed alternative therapies to Plaintiff.

232. Plaintiff would not have taken ranitidine had Plaintiff known of or been fully and adequately informed by Defendants of the true increased risks and serious dangers of taking the drug.

233. As a direct and proximate result of Defendants' conduct, Plaintiff suffered serious injuries, which resulted in damages to Plaintiff in sums in excess of the jurisdictional limits of the Court.

234. Defendants' conduct was committed with knowing, reckless, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of

consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish and deter similar conduct in the future.

EXEMPLARY / PUNITIVE DAMAGES ALLEGATIONS

235. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants were fully aware of the safety risks of ranitidine, particularly the carcinogenic potential of ranitidine as it transforms into NDMA within the chemical environment of the human body and/or during transport and/or storage. Nonetheless, Defendants deliberately crafted their label and marketing to mislead consumers.

236. This was not done by accident or through some justifiable negligence. Rather, Defendants knew they could profit by convincing consumers that ranitidine was harmless to humans, and that full disclosure of the true risks of ranitidine would limit the amount of money Defendants would make selling the drugs. Defendants' object was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Plaintiff was denied the right to make an informed decision about whether to purchase and use ranitidine-containing products, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff's rights.

237. Accordingly, Plaintiff request punitive damages against Defendants for the harms caused to Plaintiff.

FIRST CAUSE OF ACTION:

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(By Plaintiff Robert Torres Against ALL Defendants)

238. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

239. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Defendants.

240. Defendants designed, manufactured, tested, marketed, labeled, packaged,

handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their ranitidine- containing products, and in the course of same, directly marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of ranitidine.

241. At all relevant times, Defendants had a duty to properly design, manufacture, test, market, label, package, handle, distribute, store, sell, provide proper warnings, and/or take such steps as necessary to ensure their ranitidine-containing products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiff of the dangers associated with ranitidine. Defendants, as a manufacturer, seller, distributor, or repackager of pharmaceutical medication, are held to the knowledge of an expert in the field.

242. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as the packaging, storage, and handling of ranitidine.

243. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

244. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Defendants' ranitidine-containing products.

245. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as Plaintiff.

246. Defendants knew or should have known that ranitidine-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, and

physicians of the risks of exposure to ranitidine-containing products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

247. At all relevant times, Defendants' ranitidine-containing products were expected to and did reach Plaintiff without a substantial change in their anticipated or expected design as manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by the Brand-Name Manufacture, and Repackager Defendants.

248. Plaintiff was exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics.

249. At all relevant times, Plaintiff used and/or was exposed to the use of Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

250. Plaintiff could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time Plaintiff consumed the drugs. Plaintiff and his physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

251. Defendants knew or should have known that the minimal warnings disseminated with their ranitidine-containing products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

252. The information that Defendants did provide or communicate failed to contain relevant warnings, expiration dates, hazards, and precautions that would have enabled consumers such as Plaintiff to avoid using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of ranitidine-containing products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine.

253. This alleged failure to warn is not limited to the information contained on ranitidine-containing products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with ranitidine through other non-labeling mediums, *e.g.*, promotion, advertisements, public service announcements, and/or public information sources. But Defendants did not disclose these known risks through any medium.

254. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiff could not have averted his injuries.

255. Defendants' conduct, as described above, was reckless. Defendants risked the livesof consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

256. Defendants' lack of adequate warnings and instructions accompanying their ranitidine-containing products were a substantial factor in causing Plaintiff's injuries.

257. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economicloss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

258. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

SECOND CAUSE OF ACTION:

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(By Plaintiff Robert Torres Against ALL Defendants)

259. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

260. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing ranitidine-containing products into the stream of commerce. These actions were under the ultimate control and supervision of these Defendants.

261. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the ranitidine-containing products used by Plaintiff, as described herein.

262. At all relevant times, Defendants' ranitidine-containing products were designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

263. At all relevant times, the medication ingested by Plaintiff was expected to and did reach Plaintiff without a substantial change in their anticipated or expected design as manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by theBrand-Name Manufacturer and Repackager Defendants.

264. Defendants' ranitidine-containing products, as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants were defective in design and formulation in that, when they left Defendants' control, they were unreasonably dangerous, and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

265. Defendants' ranitidine-containing products, as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants were defective in design and formulation in that, when they left the hands of Defendants, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

266. At all relevant times, Defendants knew or had reason to know that ranitidine-containing products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

267. Therefore, at all relevant times, Defendants' ranitidine-containing products, as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants were defective in design and formulation, in one or more of the following ways:

a. Defendants' ranitidine-containing products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

b. Defendants' ranitidine-containing products were not reasonably safe when used in a reasonably anticipated or intended manner;

c. Defendants did not sufficiently test, investigate, or study their ranitidine-containing products and, specifically, the ability for ranitidine to transform into the carcinogenic compound NDMA within the human body;

d. Defendants did not sufficiently test, investigate, or study their ranitidine-containing products and, specifically, the stability of ranitidine and the ability for ranitidine-containing products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

e. Defendants failed to provide accurate expiration dates on the product label;

f. Defendants failed to package their ranitidine-containing products in a manner which would have preserved the safety, efficacy, quality, and purity of the product;

g. Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage of the drug;

h. Defendants knew or should have known at the time of marketing ranitidine-containing products that exposure to ranitidine could result in cancer and other severe illnesses and injuries;

i. Defendants did not conduct adequate post-marketing surveillance of their ranitidine-containing products;

j. Defendants did not conduct adequate stability testing of their product to ascertain shelf life, expiration, and proper storage, heat, and light specifications; and

k. Defendants could have employed safer alternative designs and formulations.

268. Plaintiffs used and were exposed to Defendants' ranitidine-containing products without knowledge of ranitidine's dangerous characteristics.

269. At all times relevant to this litigation, Plaintiff used and/or was exposed to the use of Defendants' ranitidine-containing products in an intended or reasonably foreseeable manner without knowledge of ranitidine's dangerous characteristics.

270. Plaintiff could not reasonably have discovered the defects and risks associated

with ranitidine-containing products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking ranitidine to cancer.

271. Exposure to ranitidine presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug. The harm caused by Defendants' ranitidine-containing products far outweighed their benefit, rendering each Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' ranitidine- containing products were and are more dangerous than alternative products, and Defendants could have designed ranitidine-containing products to make them less dangerous. Indeed, at the time Defendants designed ranitidine-containing products and their labels, the state of the industry's scientific knowledge was such that a safer, less risky design or formulation and label was attainable.

272. At the time ranitidine-containing products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' ranitidine-containing products. For example, Defendants could have provided proper warnings, expiration dates, stability information, and associated information.

273. Defendants' defective design of ranitidine-containing products was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of ranitidine- containing products, including Plaintiff.

274. The defects in Defendants' ranitidine-containing products were substantial factors in causing Plaintiffs' injuries.

275. As a direct and proximate result of Defendants' defective design of ranitidine-containing products, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

276. WHEREFORE, Plaintiff respectfully requests this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

THIRD CAUSE OF ACTION:

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(By Plaintiff Robert Torres Against ALL Defendants)

277. Plaintiff incorporates by reference each allegation set forth in preceding paragraphsas if fully stated herein.

278. At all times herein mentioned, the Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the ranitidine-containing products ingested by Plaintiff.

279. At all relevant times, the medication ingested by Plaintiff was expected to and did reach Plaintiff without a substantial change in their anticipated or expected design as manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by the Manufacturer Defendants.

280. At all relevant times, the medications ingested by Plaintiff were used in a manner that was foreseeable and intended by the Manufacturer Defendants.

281. The ranitidine ingested by Plaintiff was not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that the Manufacturer Defendants deviated materially from their design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale specifications and/or such design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale posed an unreasonable risk of harm to Plaintiff.

282. The Manufacturer Defendants' ranitidine-containing products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their healthcare providers.

283. The ranitidine-containing products create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of ranitidine-containing products because of the Manufacturer Defendants' manufacturing defects, which include but are not limited to:

a. Failure to follow CGMPs;

b. Upon information and belief, failure to adequately clean and test recovered and/or recycled solvents;

c. Failure to adequately inspect and/or test the drugs during the manufacturing process;

d. Failure to implement procedures that would reduce or eliminate NDMA levels in ranitidine-containing products;

e. Failure to implement appropriate handling instructions and storage conditions for the API and the finished drug.

284. The Manufacturer Defendants have intentionally and recklessly manufactured ranitidine-containing products with wanton and willful disregard for the rights and health of Plaintiff, and with malice, placing their economic interests above the health and safety of Plaintiff.

285. The manufacturing defects in the Manufacturer Defendants' ranitidine-containing products were substantial factors in causing Plaintiff's injuries.

286. As a direct and proximate result of Defendants' defective manufacture of ranitidine-containing products, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

287. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

FOURTH CAUSE OF ACTION:

NEGLIGENCE – FAILURE TO WARN

(By Plaintiff Robert Torres Against ALL Defendants)

288. Plaintiff incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

289. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products. Defendants knew or by the exercise of reasonable care should have known that their ranitidine-containing products were not accompanied by adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Defendants.

290. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, and otherwise released into the stream of commerce their ranitidine-containing products, and in the course of same, directly marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of ranitidine-containing products.

291. At all relevant times, Defendants had a duty to properly design, manufacture, test, market, label, package, handle, distribute, store, and sell, provide proper warnings, and take such steps as necessary to ensure their ranitidine-containing products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs of dangers associated with ranitidine. Defendants, as manufacturer, seller, distributor, or repackager of pharmaceutical medication, are held to the knowledge of an expert in the field.

292. Defendants had a continuing duty to provide appropriate and accurate warnings and instructions regarding the identity, strength, stability, expiry, quality and purity at the time of use of their products and how to properly store and handle their ranitidine-containing products.

293. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known use of ranitidine-containing products was dangerous, harmful, and injurious when used by Plaintiff in a reasonably foreseeable manner.

294. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their product and to those who would foreseeably use or be harmed by Defendants' ranitidine-containing products.

295. Defendants knew or should have known that ranitidine-containing products posed a grave risk of harm but failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the products. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting ranitidine, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the product, and were not known to end users and consumers, such as Plaintiff.

296. Defendants further breached their duty by failing to use reasonable care to adequately warn or instruct consumers (*i.e.*, the reasonably foreseeable users), such as Plaintiff, of the risks of exposure to their products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in their ranitidine-containing products and the potential for ingested ranitidine to transform into the carcinogenic NDMA

compound, and further, have made false and/or misleading statements concerning the safety of ranitidine-containing products.

297. At all relevant times, Plaintiff used and/or was exposed to excessive levels of nitrosamines through the use of Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

298. Defendants knew or should have known that the minimal warnings disseminated with their ranitidine-containing products were inadequate, failed to communicate adequate information on the dangers and identity, strength, quality and purity at the time of use of their products, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended, and reasonably foreseeable uses.

299. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to avoid using the product. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine and ranitidine-containing products; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine-containing products.

300. A reasonable company under the same or similar circumstance would have warned and instructed of the dangers of ranitidine-containing products.

301. This alleged failure to warn is not limited to the information contained on ranitidine-containing products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with ranitidine-containing products through other non-labeling mediums, *e.g.*, promotion, advertisements, public service announcements, and/or public information sources. But Defendants did not disclose these known risks through any medium.

302. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products, Plaintiff

could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiff could not have averted his injuries.

303. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

304. Defendants' lack of adequate warnings and instructions accompanying their ranitidine-containing products were a substantial factor in causing Plaintiff's injuries.

305. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

306. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

FIFTH CAUSE OF ACTION:

NEGLIGENT PRODUCT DESIGN

(By Plaintiff Robert Torres Against ALL Defendants)

307. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

308. Manufacturer and Repackager Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of ranitidine-containing products.

309. Manufacturer and Repackager Defendants owed a duty to all reasonably foreseeable users to design a safe product and to provide a label that rendered the product safe and effective.

310. Manufacturer and Repackager Defendants breached their duty by failing to use reasonable care in the design of ranitidine-containing products because the drug exposed users

tounsafe levels of the carcinogen NDMA.

311. Manufacturer and Repackager Defendants breached their duty by failing to use reasonable care in the design of ranitidine-containing products by negligently designing the drug with an inherent susceptibility to form NDMA.

312. Manufacturer and Repackager Defendants breached their duty by failing to use reasonable care in the design of ranitidine-containing products in one or more of the following ways:

a. When placed in the stream of commerce, Manufacturer and Repackager Defendants' ranitidine-containing products were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;

b. When placed in the stream of commerce, Manufacturer and Repackager Defendants' ranitidine-containing products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer and other serious illnesses when used in a reasonably anticipated manner;

c. When placed in the stream of commerce, Manufacturer and Repackager Defendants' ranitidine-containing products contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

d. Manufacturer and Repackager Defendants did not sufficiently test, investigate, or study their ranitidine-containing products and, specifically, the ability for ranitidine to transform into the carcinogenic compound NDMA within the human body;

e. Manufacturer and Repackager Defendants did not sufficiently test, investigate, or study their ranitidine-containing products identity, strength, quality and purity at the time of use of their products and, specifically, the ability for ranitidine-containing products to develop increasing levels of NDMA under anticipated and expected packaging, storage, and handling conditions;

f. Manufacturer and Repackager Defendants did not sufficiently test, investigate, or study their ranitidine-containing products identity, strength, quality and purity at the time of use of their products and, specifically, the ability for ranitidine-containing products to develop increasing levels of NDMA over time;

g. Manufacturer and Repackager Defendants failed to conduct proper stability testing and/or to set accurate recall dates for the drugs, which resulted in the formation of excess amounts of NDMA in ranitidine-containing products;

h. Manufacturer and Repackager Defendants knew or should have known at the time of marketing ranitidine-containing products that exposure to ranitidine could resultin cancer and other severe illnesses and injuries;

i. Manufacturer and Repackager Defendants did not conduct adequate post-marketing surveillance of their ranitidine-containing products; and

j. Manufacturer and Repackager Defendants could have employed safer alternative designs and formulations.

313. Exposure to ranitidine presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug.

314. Manufacturer and Repackager Defendants breached their duty to exercise reasonable care by failing to use cost effective, reasonably feasible alternative designs. There was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Manufacturer and Repackager Defendants' ranitidine-containing products.

315. A reasonable company under the same or similar circumstances would have designed a safer product.

316. Plaintiff was harmed directly and proximately by Manufacturer and Repackager Defendants' failure to use reasonable care in the design of their ranitidine-containing products. Such harm includes significant exposure to a known carcinogen, NDMA, which can cause or contribute the development of cancers.

317. Manufacturer and Repackager Defendants' defective design of ranitidine-containing products was willful, wanton, malicious, and conducted with reckless disregard for thehealth and safety of users of ranitidine-containing products, including Plaintiff.

318. The defects in Manufacturer and Repackager Defendants' ranitidine-containing products were substantial factors in causing Plaintiff's injuries.

319. As a direct and proximate result of Manufacturer and Repackager Defendants' defective design of ranitidine-containing products, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

320. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

SIXTH CAUSE OF ACTION:

NEGLIGENT MANUFACTERING

(By Plaintiff Robert Torres Against Manufacturer Defendants)

321. Plaintiff incorporates by reference each allegation set forth in preceding paragraphsas if fully stated herein.

322. At all relevant times, the Manufacturer Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the ranitidine-containing products that Plaintiff consumed.

323. Manufacturer Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products.

324. Manufacturer Defendants knew or, by the exercise of reasonable care, should have known that use of ranitidine-containing products that were carelessly manufactured or packaged was dangerous, harmful, and injurious when used by Plaintiff in a reasonably foreseeable manner.

325. Manufacturer Defendants knew or, by the exercise of reasonable care, should have known that ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of ranitidine-containing products improperly designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold.

326. Without limitation, examples of the manner in which the Manufacturer Defendants breached their duty to exercise reasonable care in manufacturing ranitidine-containing products included:

a. Failure to follow CGMPs;

b. Failure to adequately inspect and/or test the drugs during and after the manufacturing process to ensure identity, strength, quality and purity at the time of use of their products;

c. Failure to implement procedures that would reduce or eliminate NDMA levels in ranitidine-containing products;

d. Failure to conduct proper stability testing and/or to set accurate recall dates for the drugs, which resulted in the formation of excess amounts of NDMA in ranitidine-containing products; and

e. Failure to implement appropriate handling instructions and storage

conditions for the drug.

327. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality and safety of theirproduct.

328. Plaintiff was harmed directly and proximately by the Manufacturer Defendants' failure to use reasonable care in the manufacture of their ranitidine-containing products. Such harm includes significant exposure to a known carcinogen, NDMA, which can cause or contributeto the development of cancers.

329. Manufacturer Defendants' improper manufacturing of ranitidine-containing products was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of ranitidine-containing products, including Plaintiff.

330. The defects in the Manufacturer Defendants' ranitidine-containing products were substantial factors in causing Plaintiff's injuries.

331. As a direct and proximate result of the Manufacturer Defendants' improper design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

332. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

SEVENTH CAUSE OF ACTION:

GENERAL NEGLIGENCE

(By Plaintiff Robert Torres Against ALL Defendants)

333. Plaintiff incorporates by reference each allegation set forth in preceding paragraphsas if fully stated herein.

334. Defendants, directly or indirectly, designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products that were used by Plaintiff.

335. At all relevant times, Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage,

and/or sale of ranitidine-containing products, including the duty to take all reasonable steps necessary to design, manufacture, test, market, label, package, handle, distribute, store, and/or sella product that was not unreasonably dangerous to consumers and users of the product.

336. At all relevant times, Defendants had a duty to exercise reasonable care in the marketing and sale of ranitidine-containing products. Defendants owed to consumers and the general public a duty of care that included providing accurate, true, and correct information concerning the risks of using ranitidine-containing products and appropriate, complete, and accurate warnings concerning the potential adverse effects of ranitidine and, in particular, its ability to transform into the carcinogenic compound NDMA.

337. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of ranitidine and, specifically, the carcinogenic properties of NDMA when ranitidine-containing products are ingested and/or the elevated levels of NDMA that occurs when ranitidine-containing products are transported and stored.

338. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that their ranitidine-containing products were highly unstable and that ranitidine- containing products were not safe for human consumption for as long as the labeling suggested.

339. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that their ranitidine-containing products were likely to break down in the absence of sufficient packaging which would have protected the pills from heat and/or light exposure.

340. Accordingly, at all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that use of ranitidine-containing products could cause or be associated with Plaintiff's injuries, and thus create a dangerous and unreasonable risk of injury tothe users of these products, including Plaintiff.

341. Defendants also knew or, in the exercise of reasonable care, should have known that users and consumers of ranitidine-containing products were unaware of the risks and the magnitude of the risks associated with use of ranitidine-containing products.

342. As such, Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products, in that Defendants manufactured and produced defective ranitidine-containing products, which carries the

potential to transform into the carcinogenic compound NDMA; knew or had reason to know of the defects inherent in their products; knew or had reason to know that a user's or consumer's use of the products created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries. Indeed, Defendants deliberately refused to test ranitidine-containing products for NDMA levels because they knew that the chemical posed serious health risks to humans.

343. Defendants further failed to conduct stability and light sensitivity studies at all levels of the distribution and storage chain to enable them to set accurate expiration dates for their ranitidine-containing products. As such, Defendants failed to provide physicians and patients, such as Plaintiff, with accurate warnings related to their products.

344. Defendants were negligent in their marketing of ranitidine-containing products, outside of the labeling context, by failing to disclose material-risk information as part of their marketing of ranitidine-containing products, including the internet, television, and print advertisements. Nothing prevented Defendants from being honest in their promotional activities to doctors, as well as to co-Defendants further down the distribution chain, including generic manufacturers, distributors, repackagers, relabelers, and retailers, among others, and, in fact, Defendants had a duty to disclose the truth about the risks associated with ranitidine in their promotional efforts, outside of the context of labeling.

345. Defendants— designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine—were in a superior position to understand the risk of NDMA being present in and/or forming in ranitidine-containing products and had a duty towarn of these dangers.

346. Despite their ability and means to investigate, study, and test the products and to provide adequate warnings, Defendants failed to do so. Indeed, Defendants wrongfully concealed information and further made false and/or misleading statements concerning the safety and use ofranitidine-containing products.

347. Defendants' negligence included:

a. Designing, manufacturing, testing, marketing, labeling, packaging, handling, distributing, storing, and/or selling ranitidine-containing products without thorough and adequate pre- and post-market testing;

b. Designing, manufacturing, testing, marketing, labeling, packaging, handling, distributing, storing, and/or selling ranitidine-containing products while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, andstudies of ranitidine and the carcinogenic potential of NDMA as a

result of ingesting ranitidine, and, consequently, the risk of serious harm associated with human use of ranitidine-containing products;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not ranitidine-containing products were safe for their intended consumer use;

d. Failing to use reasonable and prudent care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products so as to avoid the risk of serious harm associated with the prevalent use of ranitidine-containing products;

e. Failing to design, manufacture, test, market, label, package, handle, distribute, store, and/or sell ranitidine-containing products so as to ensure they were at least as safe and effective as other medications on the market intended to treat the same symptoms;

f. Failing to undertake to provide adequate instructions, guidelines, and safety precautions regarding identity, strength, quality and purity at the time of use of their products to those persons Defendants could reasonably foresee would use ranitidine-containing products;

g. Failing to conduct proper studies at every level of the distribution chain regarding stability, as well as proper packaging and storage conditions, particularly relating to heat and light;

h. Failing to comply with CGMPs or conduct testing and due diligence in sourcing ingredients and solvents used to manufacture ranitidine-containing products;

i. Failing to comply with CGMPs or conduct testing and due diligence before designing, manufacturing, testing, marketing, labeling, packaging, handling, distributing, storing, and/or selling ranitidine-containing products, specifically as it relates to proper storage and transport of the drugs, and subsequently failing to provide proper warnings to patients and physicians concerning the same;

j. Failing to conduct proper post-market surveillance relating to the presence of NDMA in Defendants' ranitidine-containing products;

k. Failing to conduct proper post-market surveillance relating to the stability (or lackthereof) of Defendants' ranitidine-containing products;

l. Failing to report adverse events, specifically cases of cancer in patients who took ranitidine-containing products to the FDA, despite being aware of these adverse events;

m. Failing to undertake to disclose to Plaintiffs, users/consumers, and the general public that use of ranitidine-containing products presented severe risks of cancer;

n. Failing to warn Plaintiffs, consumers, and the general public that ranitidine-containing products' risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiffs and other consumers;

o. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of ranitidine-containing products;

p. Representing that their ranitidine-containing products were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose;

q. Declining to make or propose any changes to ranitidine-containing products' labeling or other promotional materials that would alert consumers and the general public of the risks of ranitidine-containing products;

r. Advertising, marketing, and recommending the use of ranitidine-containing products, while concealing and failing to disclose or warn of the dangers known (by Defendants) to be associated with or caused by the use of or exposure to ranitidine-containing products;

s. Continuing to disseminate information to consumers, including Plaintiff, that indicate or imply that Defendants' ranitidine-containing products are not unsafe for regular consumer use; and

t. Continuing to design, manufacture, test, market, label, package, handle, distribute,store, and/or sell ranitidine-containing products with the knowledge that the products were unreasonably unsafe and dangerous.

348. Defendants knew or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products.

349. Plaintiff did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to ranitidine-containing products.

350. Defendants' negligence was a substantial factor in causing Plaintiff's injuries.

351. Defendants' conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiff, with full knowledge of the dangers of their products. Defendants have made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff, about those dangers. Defendants' reckless conduct therefore warrants an award of punitive damages.

352. As a direct and proximate result of Defendants' failure to undertake to provide an

adequate warning of the risks of ranitidine-containing products, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

353. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

EIGHTH CAUSE OF ACTION:

NEGLIGENT MISREPRESENTATION

(By Plaintiff Robert Torres Against ALL Defendants)

354. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

355. At all relevant times, Manufacturer and Repackager Defendants designed, manufactured, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, stored, handled, warehoused, distributed, sold and/or otherwise placed ranitidine-containing products into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to consumers of ranitidine-containing products, including Plaintiffs.

356. Manufacturer and Repackager Defendants were negligent, reckless, and careless and owed a duty to Plaintiffs to make accurate and truthful representations regarding ranitidine-containing products, and Manufacturer and Repackager Defendants breached their duty, thereby causing Plaintiffs to suffer harm.

357. Manufacturer and Repackager Defendants represented to Plaintiff via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations described herein that:

a. ranitidine-containing products were both safe and effective for the lifetime of the product, when in fact, the drug contains unsafe levels of NDMA far in excess of the 96ng limit that increases at various points during the shipping, handling, storage, and consumption phases and as the product ages;

b. consumption of ranitidine-containing products would not result in excessive amounts of NDMA being formed in their bodies; and

c. the levels of NDMA in ranitidine-containing products have no practical clinical significance; and

d. ranitidine-containing products were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose.

358. These representations were false. Because of the unsafe levels of NDMA in ranitidine-containing products, the drug presented an unacceptable risk of causing cancer. Ranitidine-containing products are so unsafe that the FDA was compelled to order the immediate withdrawal of all ranitidine-containing products on April 1, 2020.

359. Manufacturer and Repackager Defendants knew or should have known these representations were false and negligently made them without regard for their truth.

360. Manufacturer and Repackager Defendants had a duty to accurately provide this information to Plaintiffs. In concealing this information from Plaintiff, Manufacturer and Repackager Defendants breached their duty. Manufacturer and Repackager Defendants also gained financially from, and as a result of their breach.

361. Manufacturer and Repackager Defendants intended for Plaintiff and/or his physicians to rely on these representations.

362. Each of these misrepresentations were material at the time they were made. In particular, each of the misrepresentations concerned material facts that were essential to the analysis undertaken by Plaintiff as to whether to purchase or consume ranitidine-containing products.

363. Plaintiff reasonably relied on these representations and were harmed as described herein. Plaintiff's reliance on Manufacturer and Repackager Defendants' representations was a substantial factor in causing Plaintiff's harms. Had Manufacturer and Repackager Defendants told Plaintiff the truth about the safety and composition of ranitidine-containing products, Plaintiff would not have consumed or purchased them.

364. Manufacturer and Repackager Defendants' acts and omissions as described herein were committed in reckless disregard of Plaintiff's rights, interests, and well-being to enrich Defendants.

365. As a direct and proximate result of the Manufacturer and Repackager Defendants' negligent misrepresentations concerning their ranitidine-containing products, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses,lost income, and other damages.

366. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

NINTH CAUSE OF ACTION:

BREACH OF EXPRESS WARRANTIES

(By Plaintiff Robert Torres Against ALL Defendants)

367. Plaintiff incorporates by reference each allegation set forth in preceding paragraphsas if fully stated herein.

368. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing ranitidine-containing products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

369. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products, including a duty to:

a. ensure that their products did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects; and

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to ranitidine-containing products, when making representations to consumers and the general public, including Plaintiffs.

370. As alleged throughout this pleading, the ability of Defendants to properly disclose those risks associated with ranitidine-containing products is not limited to representations made on the labeling.

371. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that ranitidine-containing products were safe to human health and the environment, effective, fit, and proper for their intended use. Defendants advertised, labeled, marketed, and promoted ranitidine-containing products, representing the quality to consumers

and the public in such a way as to induce their purchase or use, thereby making an express warranty that ranitidine-containing products would conform to the representations.

372. These express representations include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to ranitidine-containing products. Defendants knew and/or should have known that the risks expressly included in ranitidine-containing products warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendants expressly represented that ranitidine-containing products were safe and effective, that they were safe and effective for use by individuals such as Plaintiff, and/or that they were safe and effective as consumer medication.

373. The representations about ranitidine-containing products, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

374. Defendants placed ranitidine-containing products into the stream of commerce for sale and recommended their use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the use of ranitidine-containing products.

375. Defendants breached these warranties because, among other things, ranitidine-containing products were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the warranties in the following ways:

a. Defendants represented through their labeling, advertising, and marketing materials that ranitidine-containing products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of ranitidine-containing products and by expressly limiting the risks associated with use within their warnings and labels;

b. Defendants represented that the expiry dates on their products were accurate and that their ranitidine-containing products were safe for consumption throughout the end of the expiry period;

c. Defendants represented that their ranitidine-containing products were safe for human consumption without disclosing the risks of NDMA in the pills, the risk that NDMA might form over time and/or increase dramatically as a result of exposure to heat and/or light, and the risk that NDMA might form during the

digestion process; and

d. Defendants represented that ranitidine-containing products were safe for use and intentionally concealed information that demonstrated that they had carcinogenic properties, and that ranitidine-containing products, therefore, were not safer than alternatives available on the market.

376. Plaintiff detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of ranitidine-containing products in decidingto purchase the product. Plaintiff reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of ranitidine. Physicians would not have prescribed, and Plaintiff would not have purchased or used ranitidine-containing products had Defendants properly disclosed the risks associated with ranitidine, either through advertising, labeling, or any other form of disclosure.

377. Defendants had sole access to material facts concerning the nature of the risks associated with their ranitidine-containing products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiff could not have reasonably discovered that the risks expressly included in ranitidine-containing products' warnings and labels were inadequate and inaccurate.

378. Plaintiff had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning ranitidine-containing products.

379. Plaintiff used and/or was exposed to ranitidine-containing products as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, or otherwise released into the stream of commerce by Defendants.

380. Had the warnings, labels, advertisements, or promotional material for ranitidine-containing products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the products were safe for their intended use, Plaintiff could have avoided the injuries complained of herein.

381. Defendants' breach of these express warranties was a substantial factor in causing Plaintiff's harm.

382. As a direct and proximate result of Defendants' breach of these warranties, as alleged herein, Plaintiff sustained an economic loss and other injuries.

383. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein

incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

TENTH CAUSE OF ACTION:

BREACH OF IMPLIED WARRANTIES

(By Plaintiff Robert Torres Against ALL Defendants)

384. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

385. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which were and are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing ranitidine-containing products into the stream of commerce.

386. Before the time Plaintiff used ranitidine-containing products, Defendants impliedly warranted to their consumers, including Plaintiff, that ranitidine-containing products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

387. But Defendants failed to disclose that ranitidine-containing products had dangerous propensities when used as intended and that use of ranitidine-containing products carries an increased risk of developing severe injuries, including Plaintiff's injuries.

388. Plaintiff was an intended beneficiary of the implied warranties made by Defendants to purchasers of their ranitidine-containing products.

389. At all relevant times, Defendants were aware that consumers and users of their products, including Plaintiff, would use ranitidine-containing products as marketed by Defendants, which is to say that Plaintiff was a foreseeable user of ranitidine-containing products.

390. Defendants intended that ranitidine-containing products be used in the manner in which Plaintiff, in fact, used them and which Defendants impliedly warranted to be of merchantable quality, safe, and fit for this use, even though ranitidine-containing products were not adequately tested or researched.

391. In reliance upon Defendants' implied warranty, Plaintiff used ranitidine-containing products as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

392. Plaintiff could not have reasonably discovered or known of the risks of serious injury associated with ranitidine-containing products.

393. Defendants breached their implied warranty to Plaintiff in that ranitidine-containing products were not of merchantable quality, safe, or fit for their intended use, or adequately tested. Ranitidine-containing products have dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein.

394. The harm caused by Defendants' ranitidine-containing products far outweighed their benefit, rendering the products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

395. Defendants' breach of these implied warranties was a substantial factor is causing Plaintiff's harm.

396. As a direct and proximate result of Defendants' breach of implied warranties, as alleged herein, Plaintiff sustained a loss an economic loss and other injuries.

397. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

ELEVENTH CAUSE OF ACTION:

VIOLATION OF CONSUMER PROTECTION AND

DECEPTIVE TRADE PRACTICES LAWS

(By Plaintiff Robert Torres Against ALL Defendants)

398. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

399. Plaintiff used Defendants' ranitidine-containing products and suffered ascertainable losses as a result of Defendants' actions in violation of consumer protection laws.

400. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased ranitidine-containing products, and would not have incurred related medical costs and injuries.

401. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiffs for ranitidine-containing products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

402. Unfair methods of competition or deceptive acts or practices that were proscribed

by law include:

a. Representing that goods or services have characteristics, ingredients, uses benefits or qualities they do not have;

b. Representing that ranitidine-containing products are of a particular standard, quality, and grade when they are not.

c. Advertising goods or services with the intent not to sell them as advertised;

d. Over-promotion of the product with respect to, inter alia, its safety and efficacy; and

e. Engaging in fraudulent and deceptive conduct that creates a likelihood of confusion or misunderstanding.

403. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct, which created demand for ranitidine-containing products. Each aspect of Defendants' conduct combined to artificially create sales for ranitidine-containing products.

404. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products.

405. Had Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for ranitidine-containing products and would not have incurred related medical costs.

406. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to Plaintiffs constituted unfair and deceptive acts and trade practices in violation of state consumer protection statutes.

407. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes.

408. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the following consumer protection laws, including but not limited to, Cal Bus & Prof Code §§ 1750, et seq.

409. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers and sellers who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

410. Plaintiff is the type of consumers, as defined in these statutes, that these statutes were designed to protect.

411. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that ranitidine-containing products were fit to be used for the purpose for which they were intended, when in fact ranitidine-containing products were defective and dangerous, and by other acts alleged herein. These representations were made in promotional materials.

412. The actions and omissions of Defendants as alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising. Defendants were provided notice of the issues raised in this count and this MPIC by the FDA, the numerous complaints filed against them, and the many individual notice letters sent by Plaintiffs within a reasonable amount of time after the allegations of ranitidine-containing products' defects became public.

413. Defendants had actual knowledge of the defective and dangerous condition of ranitidine-containing products and failed to take any action to cure such defective and dangerous conditions.

414. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions. Defendants' unfair or deceptive acts or practices, including their misrepresentations, concealments, omissions, and suppressions of material facts, as alleged herein,had a tendency or capacity to mislead and create a false impression in consumers' minds, and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff, about the inherently defective and unreasonably dangerous nature of ranitidine-containing products.

415. Defendants had an ongoing duty to Plaintiff to refrain from unfair and deceptive practices under these statutes in the course of their business. Specifically, Defendants owed Plaintiff a duty to disclose all the material facts concerning the dangers of ranitidine-containing products because they possessed exclusive knowledge, they intentionally concealed the dangers of ranitidine from Plaintiffs, and/or they made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

416. The facts regarding ranitidine that Defendants knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a

reasonable consumer, and they were, in fact, material to Plaintiff, who consider such facts to be important to his purchase decisions with respect to ranitidine-containing products.

417. Plaintiff purchased ranitidine-containing products in reliance on Defendants' misrepresentations, omissions, concealments, and failures to disclose material facts regarding ranitidine-containing products. Had Defendants not engaged in the deceptive acts and practices alleged herein, Plaintiff would not have purchased the drug and would not have been injured.

418. Defendants' deceptive, fraudulent and unconscionable representations to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and practices.

419. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

420. Defendants' unlawful acts and practices complained of herein affect the public interest, as the violations regarding a widely sold drug were harmful to the general public.

421. Defendants' actions and omissions as identified in this MPIC show that Defendants acted willfully, maliciously and/or intentionally disregarded Plaintiff's rights so as to warrant the imposition of punitive damages, or other applicable statutory damages including double or treble damages where available.

422. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, statutory damages where applicable, including double and treble damages, together with interest, costs herein incurred, attorneys' fees and all such otherand further relief as this Court deems just and proper.

TWELVTH CAUSE OF ACTION:

UNJUST ENRICHMENT

(By Plaintiff Robert Torres Against ALL Defendants)

423. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

424. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, or otherwise released ranitidine-containing products into the stream of commerce, and therefore owed a duty of reasonable care toavoid causing harm to those that consumed it, including Plaintiff.

425. Defendants knew that ranitidine-containing products posed a grave risk of harm

but failed to warn of the dangerous risks associated with use and exposure to the products. The dangerous propensities of their products and the carcinogenic characteristics of NDMA were well known to Defendants.

426. Defendants were unjustly enriched as a result of their wrongful conduct, including through the false and misleading marketing, promotions, and advertisements that omitted disclosure that the products presented an unreasonable risk of substantial bodily injury resulting from their use.

427. Defendants requested and received a measurable benefit at the expense of Plaintiff in the form of payment for their ranitidine-containing products.

428. Defendants appreciated, recognized, and chose to accept the monetary benefits Plaintiff conferred onto Defendants at Plaintiff's detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of Plaintiff.

429. There is no justification for Defendants' enrichment. It would be inequitable, unconscionable, and unjust for Defendants to be permitted to retain these benefits because the benefits were procured as a result of their wrongful conduct.

430. Defendants wrongfully obfuscated the harm caused by their ranitidine-containing products. Thus, Plaintiff, who mistakenly enriched Defendants by relying on Defendants' misrepresentations of product safety, could not and did not know the effect that using ranitidine-containing products would have on Plaintiff's health.

431. Plaintiff is entitled to restitution of the benefits Defendants unjustly retained and/or any amounts necessary to return Plaintiff to the position he occupied prior to dealing with Defendants. Due to their wrongful conduct and the FDA action recalling ranitidine-containing products in the form of a market withdrawal, Defendants are reasonably notified that Plaintiff would expect compensation from Defendants' unjust enrichment stemming from their wrongful actions.

432. WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

433. Pursuant to California Code of Civil Procedure section 631, Plaintiff hereby demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff request the Court to enter judgment in Plaintiff's favor and against Defendants for:

a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

b. exemplary and punitive damages sufficient to punish and deter Defendants and others from future wrongful practices;

c. pre-judgment and post-judgment interest;

d. reasonable attorneys' fees as provided by law;

e. costs and expenses of these actions;

f. any other relief the Court may deem just and proper.

Dated: September 1, 2021

THE DOLAN LAW FIRM

By: K Dembowski

Christopher B. Dolan
Emile Davis, Esq.
Katelyn P. Dembowski, Esq.
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Robert Torres

CM-010

ATTORNEY OR PARTY WITHOUT ATTORNEY *(Name, State Bar number, and address):*
Christopher Dolan SBN: 165358
Emile A. Davis SBN: 208394 Katelyn P. Dembowski SBN: 337307
DOLAN LAW FIRM, PC, 1438 Market Street, SAN FRANCISCO, CA 94102
TELEPHONE NO.: 415-421-2800 FAX NO.: 415-421-2830
ATTORNEY FOR *(Name)*: ROBERT TORRES

FOR COURT USE ONLY

SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES
STREET ADDRESS: 111 North Hill Street
MAILING ADDRESS: 111 North Hill Street
CITY AND ZIP CODE: Los Angeles, 90012
BRANCH NAME: Stanley Mosk Courthouse

CASE NAME: Robert Torres v. Boehringer Ingelheim Pharmaceuticals, Inc.,

CIVIL CASE COVER SHEET

[X] **Unlimited** (Amount demanded exceeds $25,000) [ ] **Limited** (Amount demanded is $25,000 or less)

Complex Case Designation

[ ] **Counter** [ ] **Joinder**

Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

CASE NUMBER: 21STCV32491

JUDGE:

DEPT:

Items 1–6 below must be completed (see instructions on page 2).

1. Check **one** box below for the case type that best describes this case:

Auto Tort
- [ ] Auto (22)
- [ ] Uninsured motorist (46)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
- [ ] Asbestos (04)
- [x] Product liability (24)
- [ ] Medical malpractice (45)
- [ ] Other PI/PD/WD (23)

Non-PI/PD/WD (Other) Tort
- [ ] Business tort/unfair business practice (07)
- [ ] Civil rights (08)
- [ ] Defamation (13)
- [ ] Fraud (16)
- [ ] Intellectual property (19)
- [ ] Professional negligence (25)
- [ ] Other non-PI/PD/WD tort (35)

Employment
- [ ] Wrongful termination (36)
- [ ] Other employment (15)

Contract
- [ ] Breach of contract/warranty (06)
- [ ] Rule 3.740 collections (09)
- [ ] Other collections (09)
- [ ] Insurance coverage (18)
- [ ] Other contract (37)

Real Property
- [ ] Eminent domain/Inverse condemnation (14)
- [ ] Wrongful eviction (33)
- [ ] Other real property (26)

Unlawful Detainer
- [ ] Commercial (31)
- [ ] Residential (32)
- [ ] Drugs (38)

Judicial Review
- [ ] Asset forfeiture (05)
- [ ] Petition re: arbitration award (11)
- [ ] Writ of mandate (02)
- [ ] Other judicial review (39)

Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)
- [ ] Antitrust/Trade regulation (03)
- [ ] Construction defect (10)
- [ ] Mass tort (40)
- [ ] Securities litigation (28)
- [ ] Environmental/Toxic tort (30)
- [ ] Insurance coverage claims arising from the above listed provisionally complex case types (41)

Enforcement of Judgment
- [ ] Enforcement of judgment (20)

Miscellaneous Civil Complaint
- [ ] RICO (27)
- [ ] Other complaint *(not specified above)* (42)

Miscellaneous Civil Petition
- [ ] Partnership and corporate governance (21)
- [ ] Other petition *(not specified above)* (43)

2. This case [ ] is [x] is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
   a. [ ] Large number of separately represented parties
   b. [ ] Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. [ ] Substantial amount of documentary evidence
   d. [ ] Large number of witnesses
   e. [ ] Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
   f. [ ] Substantial postjudgment judicial supervision
3. Remedies sought *(check all that apply)*: a. [x] monetary b. [ ] nonmonetary; declaratory or injunctive relief c. [x] punitive
4. Number of causes of action *(specify)*: 12
5. This case [ ] is [x] is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: September 1, 2021

Katelyn P. Dembowski
(TYPE OR PRINT NAME)

K Dembowski
(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE

- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on **all** other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

Form Adopted for Mandatory Use
Judicial Council of California
CM-010 [Rev. July 1, 2007]

CIVIL CASE COVER SHEET

Cal. Rules of Court, rules 2.30, 3.220, 3.400–3.403, 3.740;
Cal. Standards of Judicial Administration, std. 3.10
www.courtinfo.ca.gov
Westlaw Doc & Form Builder

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you **must** complete and file, along with your first paper, the *Civil Case Cover Sheet* contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check **one** box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the **primary** cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than $25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the *Civil Case Cover Sheet* to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES

Auto Tort
- Auto (22)–Personal Injury/Property Damage/Wrongful Death
- Uninsured Motorist (46) (*if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto)*

Other PI/PD/WD (Personal Injury/ Property Damage/Wrongful Death) Tort
- Asbestos (04)
  - Asbestos Property Damage
  - Asbestos Personal Injury/ Wrongful Death
- Product Liability *(not asbestos or toxic/environmental)* (24)
- Medical Malpractice (45)
  - Medical Malpractice–Physicians & Surgeons
  - Other Professional Health Care Malpractice
- Other PI/PD/WD (23)
  - Premises Liability (e.g., slip and fall)
  - Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
  - Intentional Infliction of Emotional Distress
  - Negligent Infliction of Emotional Distress
  - Other PI/PD/WD

Non-PI/PD/WD (Other) Tort
- Business Tort/Unfair Business Practice (07)
- Civil Rights (e.g., discrimination, false arrest) *(not civil harassment)* (08)
- Defamation (e.g., slander, libel) (13)
- Fraud (16)
- Intellectual Property (19)
- Professional Negligence (25)
  - Legal Malpractice
  - Other Professional Malpractice *(not medical or legal)*
- Other Non-PI/PD/WD Tort (35)

Employment
- Wrongful Termination (36)
- Other Employment (15)

Contract
- Breach of Contract/Warranty (06)
  - Breach of Rental/Lease Contract *(not unlawful detainer or wrongful eviction)*
  - Contract/Warranty Breach–Seller Plaintiff *(not fraud or negligence)*
  - Negligent Breach of Contract/ Warranty
  - Other Breach of Contract/Warranty
- Collections (e.g., money owed, open book accounts) (09)
  - Collection Case–Seller Plaintiff
  - Other Promissory Note/Collections Case
- Insurance Coverage *(not provisionally complex)* (18)
  - Auto Subrogation
  - Other Coverage
- Other Contract (37)
  - Contractual Fraud
  - Other Contract Dispute

Real Property
- Eminent Domain/Inverse Condemnation (14)
- Wrongful Eviction (33)
- Other Real Property (e.g., quiet title) (26)
  - Writ of Possession of Real Property
  - Mortgage Foreclosure
  - Quiet Title
  - Other Real Property *(not eminent domain, landlord/tenant, or foreclosure)*

Unlawful Detainer
- Commercial (31)
- Residential (32)
- Drugs (38) *(if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential)*

Judicial Review
- Asset Forfeiture (05)
- Petition Re: Arbitration Award (11)
- Writ of Mandate (02)
  - Writ–Administrative Mandamus
  - Writ–Mandamus on Limited Court Case Matter
  - Writ–Other Limited Court Case Review
- Other Judicial Review (39)
  - Review of Health Officer Order
  - Notice of Appeal–Labor Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)
- Antitrust/Trade Regulation (03)
- Construction Defect (10)
- Claims Involving Mass Tort (40)
- Securities Litigation (28)
- Environmental/Toxic Tort (30)
- Insurance Coverage Claims *(arising from provisionally complex case type listed above)* (41)

Enforcement of Judgment
- Enforcement of Judgment (20)
  - Abstract of Judgment (Out of County)
  - Confession of Judgment *(non-domestic relations)*
  - Sister State Judgment
  - Administrative Agency Award *(not unpaid taxes)*
  - Petition/Certification of Entry of Judgment on Unpaid Taxes
  - Other Enforcement of Judgment Case

Miscellaneous Civil Complaint
- RICO (27)
- Other Complaint *(not specified above)* (42)
  - Declaratory Relief Only
  - Injunctive Relief Only *(non-harassment)*
  - Mechanics Lien
  - Other Commercial Complaint Case *(non-tort/non-complex)*
  - Other Civil Complaint *(non-tort/non-complex)*

Miscellaneous Civil Petition
- Partnership and Corporate Governance (21)
- Other Petition *(not specified above)* (43)
  - Civil Harassment
  - Workplace Violence
  - Elder/Dependent Adult Abuse
  - Election Contest
  - Petition for Name Change
  - Petition for Relief From Late Claim
  - Other Civil Petition

SHORT TITLE: R.Torres v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.	CASE NUMBER 21STCV32491

CIVIL CASE COVER SHEET ADDENDUM AND STATEMENT OF LOCATION (CERTIFICATE OF GROUNDS FOR ASSIGNMENT TO COURTHOUSE LOCATION)

This form is required pursuant to Local Rule 2.3 in all new civil case filings in the Los Angeles Superior Court.

Step 1: After completing the Civil Case Cover Sheet (Judicial Council form CM-010), find the exact case type in Column A that corresponds to the case type indicated in the Civil Case Cover Sheet.

Step 2: In Column B, check the box for the type of action that best describes the nature of the case.

Step 3: In Column C, circle the number which explains the reason for the court filing location you have chosen.

Applicable Reasons for Choosing Court Filing Location (Column C)

1. Class actions must be filed in the Stanley Mosk Courthouse, Central District.
2. Permissive filing in central district.
3. Location where cause of action arose.
4. Mandatory personal injury filing in North District.
5. Location where performance required or defendant resides.
6. Location of property or permanently garaged vehicle.
7. Location where petitioner resides.
8. Location wherein defendant/respondent functions wholly.
9. Location where one or more of the parties reside.
10. Location of Labor Commissioner Office.
11. Mandatory filing location (Hub Cases – unlawful detainer, limited non-collection, limited collection, or personal injury).

	A Civil Case Cover Sheet Category No.	B Type of Action (Check only one)	C Applicable Reasons - See Step 3 Above
Auto Tort	Auto (22)	☐ A7100 Motor Vehicle - Personal Injury/Property Damage/Wrongful Death	1, 4, 11
	Uninsured Motorist (46)	☐ A7110 Personal Injury/Property Damage/Wrongful Death – Uninsured Motorist	1, 4, 11
Other Personal Injury/ Property Damage/ Wrongful Death Tort	Asbestos (04)	☐ A6070 Asbestos Property Damage ☐ A7221 Asbestos - Personal Injury/Wrongful Death	1, 11 1, 11
	Product Liability (24)	☑ A7260 Product Liability (not asbestos or toxic/environmental)	1, 4, 11
	Medical Malpractice (45)	☐ A7210 Medical Malpractice - Physicians & Surgeons ☐ A7240 Other Professional Health Care Malpractice	1, 4, 11 1, 4, 11
	Other Personal Injury Property Damage Wrongful Death (23)	☐ A7250 Premises Liability (e.g., slip and fall) ☐ A7230 Intentional Bodily Injury/Property Damage/Wrongful Death (e.g., assault, vandalism, etc.) ☐ A7270 Intentional Infliction of Emotional Distress ☐ A7220 Other Personal Injury/Property Damage/Wrongful Death	1, 4, 11 1, 4, 11 1, 4, 11 1, 4, 11

SHORT TITLE: R.Torres v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.	CASE NUMBER

	A Civil Case Cover Sheet Category No.	B Type of Action (Check only one)	C Applicable Reasons - See Step 3 Above
Non-Personal Injury/ Property Damage/ Wrongful Death Tort	Business Tort (07)	☐ A6029 Other Commercial/Business Tort (not fraud/breach of contract)	1, 2, 3
	Civil Rights (08)	☐ A6005 Civil Rights/Discrimination	1, 2, 3
	Defamation (13)	☐ A6010 Defamation (slander/libel)	1, 2, 3
	Fraud (16)	☐ A6013 Fraud (no contract)	1, 2, 3
	Professional Negligence (25)	☐ A6017 Legal Malpractice ☐ A6050 Other Professional Malpractice (not medical or legal)	1, 2, 3 1, 2, 3
	Other (35)	☐ A6025 Other Non-Personal Injury/Property Damage tort	1, 2, 3
Employment	Wrongful Termination (36)	☐ A6037 Wrongful Termination	1, 2, 3
	Other Employment (15)	☐ A6024 Other Employment Complaint Case ☐ A6109 Labor Commissioner Appeals	1, 2, 3 10
Contract	Breach of Contract/ Warranty (06) (not insurance)	☐ A6004 Breach of Rental/Lease Contract (not unlawful detainer or wrongful eviction) ☐ A6008 Contract/Warranty Breach -Seller Plaintiff (no fraud/negligence) ☐ A6019 Negligent Breach of Contract/Warranty (no fraud) ☐ A6028 Other Breach of Contract/Warranty (not fraud or negligence)	2, 5 2, 5 1, 2, 5 1, 2, 5
	Collections (09)	☐ A6002 Collections Case-Seller Plaintiff ☐ A6012 Other Promissory Note/Collections Case ☐ A6034 Collections Case-Purchased Debt (Charged Off Consumer Debt Purchased on or after January 1, 2014)	5, 6, 11 5, 11 5, 6, 11
	Insurance Coverage (18)	☐ A6015 Insurance Coverage (not complex)	1, 2, 5, 8
	Other Contract (37)	☐ A6009 Contractual Fraud ☐ A6031 Tortious Interference ☐ A6027 Other Contract Dispute(not breach/insurance/fraud/negligence)	1, 2, 3, 5 1, 2, 3, 5 1, 2, 3, 8, 9
Real Property	Eminent Domain/Inverse Condemnation (14)	☐ A7300 Eminent Domain/Condemnation Number of parcels_____	2, 6
	Wrongful Eviction (33)	☐ A6023 Wrongful Eviction Case	2, 6
	Other Real Property (26)	☐ A6018 Mortgage Foreclosure ☐ A6032 Quiet Title ☐ A6060 Other Real Property (not eminent domain, landlord/tenant, foreclosure)	2, 6 2, 6 2, 6
Unlawful Detainer	Unlawful Detainer-Commercial (31)	☐ A6021 Unlawful Detainer-Commercial (not drugs or wrongful eviction)	6, 11
	Unlawful Detainer-Residential (32)	☐ A6020 Unlawful Detainer-Residential (not drugs or wrongful eviction)	6, 11
	Unlawful Detainer-Post-Foreclosure (34)	☐ A6020F Unlawful Detainer-Post-Foreclosure	2, 6, 11
	Unlawful Detainer-Drugs (38)	☐ A6022 Unlawful Detainer-Drugs	2, 6, 11

SHORT TITLE: R.Torres v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.	CASE NUMBER

	A Civil Case Cover Sheet Category No.	B Type of Action (Check only one)	C Applicable Reasons - See Step 3 Above
Judicial Review	Asset Forfeiture (05)	☐ A6108 Asset Forfeiture Case	2, 3, 6
	Petition re Arbitration (11)	☐ A6115 Petition to Compel/Confirm/Vacate Arbitration	2, 5
	Writ of Mandate (02)	☐ A6151 Writ - Administrative Mandamus ☐ A6152 Writ - Mandamus on Limited Court Case Matter ☐ A6153 Writ - Other Limited Court Case Review	2, 8 2 2
	Other Judicial Review (39)	☐ A6150 Other Writ /Judicial Review	2, 8
Provisionally Complex Litigation	Antitrust/Trade Regulation (03)	☐ A6003 Antitrust/Trade Regulation	1, 2, 8
	Construction Defect (10)	☐ A6007 Construction Defect	1, 2, 3
	Claims Involving Mass Tort (40)	☐ A6006 Claims Involving Mass Tort	1, 2, 8
	Securities Litigation (28)	☐ A6035 Securities Litigation Case	1, 2, 8
	Toxic Tort Environmental (30)	☐ A6036 Toxic Tort/Environmental	1, 2, 3, 8
	Insurance Coverage Claims from Complex Case (41)	☐ A6014 Insurance Coverage/Subrogation (complex case only)	1, 2, 5, 8
Enforcement of Judgment	Enforcement of Judgment (20)	☐ A6141 Sister State Judgment ☐ A6160 Abstract of Judgment ☐ A6107 Confession of Judgment (non-domestic relations) ☐ A6140 Administrative Agency Award (not unpaid taxes) ☐ A6114 Petition/Certificate for Entry of Judgment on Unpaid Tax ☐ A6112 Other Enforcement of Judgment Case	2, 5, 11 2, 6 2, 9 2, 8 2, 8 2, 8, 9
Miscellaneous Civil Complaints	RICO (27)	☐ A6033 Racketeering (RICO) Case	1, 2, 8
	Other Complaints (Not Specified Above) (42)	☐ A6030 Declaratory Relief Only ☐ A6040 Injunctive Relief Only (not domestic/harassment) ☐ A6011 Other Commercial Complaint Case (non-tort/non-complex) ☐ A6000 Other Civil Complaint (non-tort/non-complex)	1, 2, 8 2, 8 1, 2, 8 1, 2, 8
Miscellaneous Civil Petitions	Partnership Corporation Governance (21)	☐ A6113 Partnership and Corporate Governance Case	2, 8
	Other Petitions (Not Specified Above) (43)	☐ A6121 Civil Harassment ☐ A6123 Workplace Harassment ☐ A6124 Elder/Dependent Adult Abuse Case ☐ A6190 Election Contest ☐ A6110 Petition for Change of Name/Change of Gender ☐ A6170 Petition for Relief from Late Claim Law ☐ A6100 Other Civil Petition	2, 3, 9 2, 3, 9 2, 3, 9 2 2, 7 2, 3, 8 2, 9

SHORT TITLE: R.Torres v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.	CASE NUMBER

Step 4: Statement of Reason and Address: Check the appropriate boxes for the numbers shown under Column C for the type of action that you have selected. Enter the address which is the basis for the filing location, including zip code. (No address required for class action cases).

REASON: ☐ 1. ☐ 2. ☐ 3. ☐ 4. ☐ 5. ☐ 6. ☐ 7. ☐ 8. ☐ 9. ☐ 10. ☑ 11.			ADDRESS: 13310 Telegraph Road
CITY: Santa Fe Springs	STATE: CA	ZIP CODE: 90670	

Step 5: Certification of Assignment: I certify that this case is properly filed in the Central District of the Superior Court of California, County of Los Angeles [Code Civ. Proc., §392 et seq., and Local Rule 2.3(a)(1)(E)].

Dated: September 1, 2021

K Dembowski

(SIGNATURE OF ATTORNEY/FILING PARTY)

PLEASE HAVE THE FOLLOWING ITEMS COMPLETED AND READY TO BE FILED IN ORDER TO PROPERLY COMMENCE YOUR NEW COURT CASE:

1. Original Complaint or Petition.
2. If filing a Complaint, a completed Summons form for issuance by the Clerk.
3. Civil Case Cover Sheet, Judicial Council form CM-010.
4. Civil Case Cover Sheet Addendum and Statement of Location form, LACIV 109, LASC Approved 03-04 (Rev. 02/16).
5. Payment in full of the filing fee, unless there is court order for waiver, partial or scheduled payments.
6. A signed order appointing the Guardian ad Litem, Judicial Council form CIV-010, if the plaintiff or petitioner is a minor under 18 years of age will be required by Court in order to issue a summons.
7. Additional copies of documents to be conformed by the Clerk. Copies of the cover sheet and this addendum must be served along with the summons and complaint, or other initiating pleading in the case.

Clear

SUPERIOR COURT OF CALIFORNIA COUNTY OF LOS ANGELES	Reserved for Clerk's File Stamp FILED Superior Court of California County of Los Angeles 09/01/2021 Sherri R. Carter, Executive Officer / Clerk of Court By: N. Alvarez Deputy
COURTHOUSE ADDRESS: Spring Street Courthouse 312 North Spring Street, Los Angeles, CA 90012	
NOTICE OF CASE ASSIGNMENT **UNLIMITED CIVIL CASE**	
Your case is assigned for all purposes to the judicial officer indicated below.	CASE NUMBER: 21STCV32491

THIS FORM IS TO BE SERVED WITH THE SUMMONS AND COMPLAINT

	ASSIGNED JUDGE	DEPT	ROOM			ASSIGNED JUDGE	DEPT	ROOM
✔	Serena R. Murillo	29						

Given to the Plaintiff/Cross-Complainant/Attorney of Record

on 09/02/2021 (Date)

Sherri R. Carter, Executive Officer / Clerk of Court

By N. Alvarez, Deputy Clerk

INSTRUCTIONS FOR HANDLING UNLIMITED CIVIL CASES

The following critical provisions of the California Rules of Court, Title 3, Division 7, as applicable in the Superior Court, are summarized for your assistance.

APPLICATION
The Division 7 Rules were effective January 1, 2007. They apply to all general civil cases.

PRIORITY OVER OTHER RULES
The Division 7 Rules shall have priority over all other Local Rules to the extent the others are inconsistent.

CHALLENGE TO ASSIGNED JUDGE
A challenge under Code of Civil Procedure Section 170.6 must be made within **15** days after notice of assignment for all purposes to a judge, or if a party has not yet appeared, within 15 days of the first appearance.

TIME STANDARDS
Cases assigned to the Independent Calendaring Courts will be subject to processing under the following time standards:

COMPLAINTS
All complaints shall be served within 60 days of filing and proof of service shall be filed within 90 days.

CROSS-COMPLAINTS
Without leave of court first being obtained, no cross-complaint may be filed by any party after their answer is filed. Cross-complaints shall be served within 30 days of the filing date and a proof of service filed within 60 days of the filing date.

STATUS CONFERENCE
A status conference will be scheduled by the assigned Independent Calendar Judge no later than 270 days after the filing of the complaint. Counsel must be fully prepared to discuss the following issues: alternative dispute resolution, bifurcation, settlement, trial date, and expert witnesses.

FINAL STATUS CONFERENCE
The Court will require the parties to attend a final status conference not more than 10 days before the scheduled trial date. All parties shall have motions in limine, bifurcation motions, statements of major evidentiary issues, dispositive motions, requested form jury instructions, special jury instructions, and special jury verdicts timely filed and served prior to the conference. These matters may be heard and resolved at this conference. At least five days before this conference, counsel must also have exchanged lists of exhibits and witnesses, and have submitted to the court a brief statement of the case to be read to the jury panel as required by Chapter Three of the Los Angeles Superior Court Rules.

SANCTIONS
The court will impose appropriate sanctions for the failure or refusal to comply with Chapter Three Rules, orders made by the Court, and time standards or deadlines established by the Court or by the Chapter Three Rules. Such sanctions may be on a party, or if appropriate, on counsel for a party.

This is not a complete delineation of the Division 7 or Chapter Three Rules, and adherence only to the above provisions is therefore not a guarantee against the imposition of sanctions under Trial Court Delay Reduction. Careful reading and compliance with the actual Chapter Rules is imperative.

Class Actions
Pursuant to Local Rule 2.3, all class actions shall be filed at the Stanley Mosk Courthouse and are randomly assigned to a complex judge at the designated complex courthouse. If the case is found not to be a class action it will be returned to an Independent Calendar Courtroom for all purposes.

***Provisionally Complex Cases**
Cases filed as provisionally complex are initially assigned to the Supervising Judge of complex litigation for determination of complex status. If the case is deemed to be complex within the meaning of California Rules of Court 3.400 et seq., it will be randomly assigned to a complex judge at the designated complex courthouse. If the case is found not to be complex, it will be returned to an Independent Calendar Courtroom for all purposes.

SUM-100

SUMMONS
(CITACION JUDICIAL)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

NOTICE TO DEFENDANT: BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM FREMONT, INC.; SANOFI US SERVICES, INC; SANOFI-AVENTIS U.S. LLC; GLAXOSMITHKLINE, LLC; PFIZER, INC.; WALMART, INC; COSTCO WHOLESALE CORPORATION; and DOES 1-100
(AVISO AL DEMANDADO):

YOU ARE BEING SUED BY PLAINTIFF: ROBERT TORRES
(LO ESTÁ DEMANDANDO EL DEMANDANTE):

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (*www.lawhelpcalifornia.org*), the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of $10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case.
¡AVISO! *Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.*

*Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (*www.sucorte.ca.gov*), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.*

*Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (*www.lawhelpcalifornia.org*), en el Centro de Ayuda de las Cortes de California, (*www.sucorte.ca.gov*) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de $10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.*

The name and address of the court is:
(El nombre y dirección de la corte es):
LOS ANGELES SUPERIOR COURT
STANLEY MOSK COURTHOUSE
111 NORTH HILL STREET, LOS ANGELES, CA 90012

CASE NUMBER:
(Número del Caso):
21STCV32491

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:
(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):
CHRISTOPHER B DOLAN
DOLAN LAW FIRM, PC, 1438 Market Street, SAN FRANCISCO, CA 94102 415-421-2800

Sherri R. Carter Executive Officer / Clerk of Court

DATE: 09/01/2021 (Fecha)
Clerk, by (Secretario) N. Alvarez, Deputy (Adjunto)

(For proof of service of this summons, use Proof of Service of Summons *(form POS-010).)*
(Para prueba de entrega de esta citatión use el formulario Proof of Service of Summons, *(POS-010)).*

[SEAL]

NOTICE TO THE PERSON SERVED: You are served
1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of *(specify):*
3. ☐ on behalf of *(specify):*
   under: ☐ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
   ☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
   ☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
   ☐ other *(specify):*
4. ☐ by personal delivery on *(date)*:

SUPERIOR COURT OF CALIFORNIA COUNTY OF LOS ANGELES	Reserved for Clerk's File Stamp FILED Superior Court of California County of Los Angeles 09/29/2021 Sherri R. Carter, Executive Officer / Clerk of Court By: A. Munoz Deputy
COURTHOUSE ADDRESS: Spring Street Courthouse 312 North Spring Street, Los Angeles, CA 90012	
PLAINTIFF/PETITIONER: Robert Torres	
DEFENDANT/RESPONDENT: Boehringer Ingelheim Pharmaceuticals, Inc et al	
CERTIFICATE OF MAILING	CASE NUMBER: 21STCV32491

I, the below-named Executive Officer/Clerk of the above-entitled court, do hereby certify that I am not a party to the cause herein, and that on this date I served the PI General Order, Standing Order re PI Procedures and Hearing Dates upon each party or counsel named below by placing the document for collection and mailing so as to cause it to be deposited in the United States mail at the courthouse in Los Angeles, California, one copy of the original filed/entered herein in a separate sealed envelope to each address as shown below with the postage thereon fully prepaid, in accordance with standard court practices.

Katelyn Patricia Dembowski
Dolan Law Firm PC
1438 Market St
San Francisco, CA 94102

Sherri R. Carter, Executive Officer / Clerk of Court

Dated: 09/29/2021

By: A. Munoz
Deputy Clerk

CERTIFICATE OF MAILING

2018-SJ-007-00

FILED
Superior Court of California
County of Los Angeles
APR 16 2018
Sherri R. Carter, Executive Officer/Clerk
By Stephanie Chung Deputy

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

IN RE PERSONAL INJURY COURT ("PI COURT") PROCEDURES, **CENTRAL DISTRICT** (EFFECTIVE APRIL 16, 2018)	) CASE NO.: 21STCV32491)) STANDING ORDER RE: PERSONAL) INJURY PROCEDURES, CENTRAL) DISTRICT))

DEPARTMENT: 2☐ 3☐ 4☐ 5☐ 7☐

FINAL STATUS CONFERENCE ("FSC"):

- **DATE:** 02/15/2023 **AT 10:00 A.M.**

TRIAL:

- **DATE:** 03/01/2023 **AT 8:30 A.M.**

OSC RE DISMISSAL (CODE CIV. PROC., § 583.210):

- **DATE:** 08/28/2024 **AT 8:30 A.M.**

TO EACH PARTY AND TO THE ATTORNEY OF RECORD FOR EACH PARTY:

Pursuant to the California Code of Civil Procedure ("C.C.P."), the California Rules of Court ("C.R.C.") and the Los Angeles County Court Rules ("Local Rules"), the Los Angeles Superior Court ("LASC" or "Court") HEREBY AMENDS AND SUPERSEDES THE AUGUST 10, 2017 SEVENTH AMENDED GENERAL ORDER AND, GENERALLY, ORDERS AS FOLLOWS IN THIS AND ALL OTHER GENERAL JURISDICTION PERSONAL INJURY ACTIONS FILED IN THE CENTRAL DISTRICT.

1. To ensure proper assignment to a PI Court, Plaintiff(s) must carefully fill out the Civil Case Cover Sheet Addendum (form LACIV 109). The Court defines "personal injury" as:

> "an unlimited civil case described on the Civil Case Cover Sheet Addendum and Statement of Location (LACIV 109) as Motor Vehicle-Personal Injury/Property Damage/Wrongful Death; Personal Injury/Property Damage/Wrongful Death-Uninsured Motorist; Product Liability (other than asbestos or toxic/environmental); Medical Malpractice-Physicians & Surgeons; Other Professional Health Care Malpractice; Premises Liability; Intentional Bodily Injury/Property Damage/Wrongful Death; or Other Personal Injury/Property Damage/Wrongful Death. An action for intentional infliction of emotional distress, defamation, civil rights/discrimination, or malpractice (other than medical malpractice), is not included in this definition. An action for injury to real property is not included in this definition." (Local Rule 2.3(a)(1)(A).)

Consistent with Local Rule 2.3(a)(1)(A), the Court will assign a case to the PI Courts if plaintiff(s) check any of the following boxes in the Civil Case Cover Sheet Addendum:

A7100 Motor Vehicle – Personal Injury/Property Damage/Wrongful Death

A7110 Personal Injury/Property Damage/Wrongful Death – Uninsured Motorist

A7260 Product Liability (not asbestos or toxic/environmental)

A7210 Medical Malpractice – Physicians & Surgeons

A7240 Medical Malpractice – Other Professional Health Care Malpractice

A7250 Premises Liability (e.g., slip and fall)

A7230 Intentional Bodily Injury/Property Damage/Wrongful Death (e.g., assault, vandalism etc.)

A7220 Other Personal Injury/Property Damage/Wrongful Death

The Court will not assign cases to the PI Courts if plaintiff(s) check any boxes elsewhere in the Civil Case Cover Sheet Addendum (any boxes on pages two and three of that form).

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The Court sets the above dates in this action in the PI Court circled above (Department 2, 3, 4, 5, or 7) at the Spring Street Courthouse, 312 North Spring Street, Los Angeles, CA 90012. (C.R.C. Rules 3.714(b)(3), 3.729.)

FILING OF DOCUMENTS

2. Parties may file documents in person at the filing window on the first floor of the Stanley Mosk Courthouse (111 N. Hill Street, Los Angeles, CA 90012) or by U.S. Mail or e-Delivery, which is available online at *www.lacourt.org* (link on homepage). Please note that filings are no longer accepted via facsimile and must be filed either in person, via U.S. mail or via e-Delivery. Claims involving an attorney-client fee dispute, documents in which the filing party is a minor, legally incompetent person, or person for whom a conservator has been appointed, requests to waive court fees (FW-001) and requests for accommodations by persons with disabilities (MC-410), may not be filed via e-Delivery.

SERVICE OF SUMMONS AND COMPLAINT

3. Plaintiff(s) shall serve the summons and complaint in this action upon defendant(s) as soon as possible but no later than three years from the date when the complaint is filed. (C.C.P. § 583.210, subd.(a).) On the OSC re Dismissal date noted above, the PI Court will dismiss the action and/or all unserved parties unless the plaintiff(s) show cause why the action or the unserved parties should not be dismissed. (C.C.P. §§ 583.250; 581, subd. (b)(4).)

4. The Court sets the above trial and FSC dates on condition that plaintiff(s) effectuate service on defendant(s) of the summons and complaint within six months of filing the complaint.

5. The PI Court will dismiss the case without prejudice pursuant to C.C.P. § 581 when no party appears for trial.

STIPULATIONS TO CONTINUE TRIAL

6. Provided that all parties agree (and there is no violation of the "five-year rule," C.C.P. § 583.310), the parties may advance or continue any trial date in the PI Courts without showing good cause or articulating any reason or justification for the change. To continue or advance a trial date, the parties (or their counsel of record) should jointly execute and submit (at the filing window on the first floor of the Stanley Mosk Courthouse, via U.S. mail or via e-Delivery; fee

required) a Stipulation to Continue Trial, FSC and Related Motion/Discovery Dates (form LACIV CTRL-242, available on the court's website, Personal Injury Court link). The PI Courts schedule FSCs for 10:00 a.m., eight (8) court days before the trial date. Parties seeking to continue the trial and FSC dates shall file the Stipulation at least eight court days before the FSC date. Parties seeking to advance the trial and FSC dates shall file the Stipulation at least eight court days before the proposed advanced FSC date. (C.C.P. § 595.2; Govt. Code § 70617, subd. (c)(2).) In selecting a new trial date, parties should avoid setting on any Monday, or the Tuesday following a court holiday. Parties may submit a maximum of two stipulations to continue trial, for a total continuance of six months. Subsequent requests to continue trial will be granted upon a showing of good cause by noticed motion. This rule is retroactive so that any previously granted stipulation to continue trial will count toward the maximum number of allowed continuances.

NO CASE MANAGEMENT CONFERENCES

7. The PI Courts do not conduct Case Management Conferences. The parties need not file a Case Management Statement.

LAW AND MOTION

8. Any documents with declarations and/or exhibits must be tabbed. (C.R.C. Rule 3.1110(f).) All depositions excerpts referenced in briefs must be marked on the transcripts attached as exhibits. (C.R.C. Rule 3.1116(c).)

CHAMBERS COPIES REQUIRED

9. In addition to filing original motion papers at the filing window on the first floor of the Stanley Mosk Courthouse, via U.S. mail or via e-Delivery, the parties must deliver, directly to the PI Court courtrooms at the Spring Street Courthouse, an extra copy (marked "Chambers Copy") of reply briefs and all other motion papers filed less than seven (7) court days before a hearing calendared in the PI Courts. The PI Courts also strongly encourage the parties filing and opposing lengthy motions, such as motions for summary judgment/adjudication, to submit one or more three-ring binders organizing the chambers copy behind tabs.

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RESERVATION HEARING DATE

10. Parties are directed to reserve hearing dates for motions in the PI Courts using the Court Reservation System (CRS) available online at *www.lacourt.org* (link on homepage). After reserving a motion hearing date, the reservation requestor must submit the papers for filing with the reservation receipt (CRS) number printed on the face page of the document under the caption and attach the reservation receipt as the last page. Parties or counsel who are unable to utilize the online CRS may reserve a motion hearing date by calling the PI Court courtroom, Monday through Friday, between 3:00 p.m. and 4:00 p.m.

WITHDRAWAL OF MOTIONS

11. California Rules of Court, Rule 3.1304(b) requires a moving party to notify the court immediately if a matter will not be heard on the scheduled date. In keeping with that rule, the PI Courts urge parties who amend pleadings in response to demurrers to file amended pleadings before the date when opposition to the demurrer is due so that the PI Courts do not needlessly prepare tentative rulings on demurrers.

DISCOVERY MOTIONS

12. The purpose of an Informal Discovery Conference ("IDC") is to assist the parties to resolve and/or narrow the scope of discovery disputes. Lead trial counsel on each side, or another attorney with full authority to make binding agreements, must attend in person. The PI judges have found that, in nearly every case, the parties amicably resolve disputes with the assistance of the Court.

13. Parties **must** participate in an IDC **before** a Motion to Compel Further Responses to Discovery will be heard unless the moving party submits evidence, by way of declaration, that the opposing party has failed or refused to participate in an IDC. Scheduling or participating in an IDC does not automatically extend any deadlines imposed by the Code of Civil Procedure for noticing and filing discovery motions. Ideally, the parties should participate in an IDC before a motion is filed because the IDC may avoid the necessity of a motion or reduce its scope. Because of that possibility, attorneys are encouraged to stipulate to extend the 45 (or 60) day deadline for filing a motion to compel further discovery responses in order to allow time to participate in an

IDC.

If parties do not stipulate to extend the deadlines, the moving party may file the motion to avoid it being deemed untimely. However, the IDC must take place before the motion is heard so it is suggested that the moving party reserve a date for the motion hearing that is at least 60 days after the date when the IDC reservation is made. Motions to Compel Further Discovery Responses are heard at 10:00 a.m. If the IDC is not productive, the moving party may advance the hearing on a Motion to Compel Further Discovery Responses on any available hearing date that complies with the notice requirements of the Code of Civil Procedure.

14. Parties are directed to reserve IDC dates in the PI Courts using CRS available online at www.lacourt.org (link on homepage). Parties are to meet and confer regarding the available dates in CRS prior to accessing the system. After reserving the IDC date, the reservation requestor must file in the appropriate department and serve an Informal Discovery Conference Form for Personal Injury Courts, from LACIV 239 (revised 12/14 or later), at least 15 court days prior to the conference and attach the CRS reservation receipt as the last page. The opposing party may file and serve a responsive IDC form, briefly setting forth that party's response, at least 10 court days prior to the IDC.

15. Time permitting, the PI Hub judges may be available to participate in IDCs to try to resolve other types of discovery disputes.

EX PARTE APPLICATIONS

16. Under the California Rules of Court, courts may only grant *ex parte* relief upon a showing, by admissible evidence, that the moving party will suffer "irreparable harm," "immediate danger," or where the moving party identifies "a statutory basis for granting relief ex parte." (C.R.C. Rule 3.1202(c).) The PI Courts have no capacity to hear multiple *ex parte* applications or to shorten time to add hearings to their fully booked motion calendars. The PI Courts do not regard the Court's unavailability for timely motion hearings as an "immediate danger" or threat of "irreparable harm" justifying *ex parte* relief. Instead of seeking *ex parte* relief, the moving party should reserve the earliest available motion hearing date (even if it is after the scheduled trial date) and should file a motion to continue trial. Parties should also check

the Court Reservation System from time to time because earlier hearing dates may become available as cases settle or hearings are taken off calendar.

REQUEST FOR TRANSFER TO INDEPENDENT CALENDAR DEPARTMENT

17. Parties seeking to transfer a case from a PI Court to an Independent Calendar ("I/C") Court shall file (at the filing window on the first floor of the Stanley Mosk Courthouse, via U.S. mail or via e-Delivery) and serve the Court's "Motion to Transfer Complicated Personal Injury Case to Independent Calendar Court" (form LACIV 238, available on the Court's website under the PI Courts link). The PI Courts will transfer a matter to an I/C Court if the case is not a "Personal Injury" case as defined in this Order, or if it is "complicated." In determining whether a personal injury case is "complicated" the PI Courts will consider, among other things, the number of pretrial hearings or the complexity of issues presented.

18. Parties opposing a motion to transfer have five court days to file (at the filing window on the first floor of the Stanley Mosk Courthouse, via U.S. mail or via e-Delivery) an Opposition (using the same LACIV 238 Motion to Transfer form).

19. The PI Courts will not conduct a hearing on any Motion to Transfer to I/C Court. Although the parties may stipulate to transfer a case to an Independent Calendar Department, the PI Courts will make an independent determination whether to transfer the case or not.

FINAL STATUS CONFERENCE

20. Parties shall comply with the requirements of the PI Courts' "First Amended Standing Order Re Final Status Conference," which shall be served with the summons and complaint.

JURY FEES

21. Parties must pay jury fees no later than 365 calendar days after the filing of the initial complaint. (C. C. P. § 631, subds. (b) and (c).)

JURY TRIALS

22. The PI Courts do not conduct jury trials. On the trial date, a PI Court will contact the Master Calendar Court, Department One, in the Stanley Mosk Courthouse. Department One will assign cases out for trial to dedicated Civil Trial Courtrooms and designated Criminal Courtrooms.

SANCTIONS

23. The Court has discretion to impose sanctions for any violation of this general order. (C.C.P. §§ 128.7, 187 and Gov. Code, § 68608, subd. (b).)

Dated: April 16, 2018

Debre K Weintraub

Debre K. Weintraub
Supervising Judge of Civil Courts
Los Angeles Superior Court